

HEARING DATE AND TIME: May 13, 2015 at 11:00 a.m. (Eastern Time)

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**UNITED STATES BANKRUPTCY COURT
SOUTHERN DISTRICT OF NEW YORK**

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In re	:
	:
SIGA TECHNOLOGIES, INC.,	:
	:
Debtor.	:
	:
-----X	

Chapter 11 Case No.
14-12623 (SHL)

**DEBTOR'S REPLY TO OBJECTIONS
TO MOTION OF DEBTOR FOR ENTRY OF ORDER
DISBANDING STATUTORY CREDITORS' COMMITTEE**

TO THE HONORABLE SEAN H. LANE,
UNITED STATES BANKRUPTCY JUDGE:

SIGA Technologies, Inc., as debtor and debtor in possession (the “**Debtor**” or “**SIGA**”), for its omnibus reply to the objections of (i) the United States Trustee (the “**U.S. Trustee**”) and (ii) the statutory creditors’ committee (the “**Committee**”) to the Motion of Debtor for Entry of Order Disbanding Statutory Creditors’ Committee (ECF No. 384) (collectively, the “**Objections**”), respectfully represents:

Preliminary Statement

1. By Motion, dated April 29, 2015 (ECF No. 384) (the “**Motion to Disband**”),¹ the Debtor is seeking to disband the Committee for a simple reason: There is only one eligible member of the Committee—PharmAthene, the Debtor’s long-time litigation adversary—and under these circumstances, the continued existence of the Committee, with all of the attendant costs and expenses, is neither appropriate nor warranted.

2. The U.S. Trustee and the Committee each filed objections to the Motion to Disband (respectively, the “**U.S. Trustee Objection**” and the “**Committee Objection**”). Distilled to their essentials, the Objections assert that (a) there is no authority for the Court to disband the Committee, ignoring the recent decision *In re City of Detroit, Michigan*, 519 B.R. 673 (Bankr. E.D. Mich. 2014), expressly finding the Bankruptcy Court had authority to disband an official committee of unsecured creditors, a decision that both the Committee and the U.S. Trustee fail to call to the Court’s attention; (b) the Committee no longer is a committee of one because of the recent appointment of Patheon Manufacturing Services, LLC (“**Patheon**”); and (c) a committee is necessary to monitor and supervise the Debtor, to engage in plan negotiations with the Debtor, and to expedite the Debtor’s prompt emergence from chapter 11. Lastly, obviously concerned about the merits of the Committee Objection, the Committee already requests a stay pending appeal of the Court’s order if it grants the Motion to Disband, thereby compelling SIGA to continue to “incur the costs of [the Committee’s] professional advisors during the appeals process.” Committee Objection ¶ 39.

¹ Capitalized terms used herein and not otherwise defined herein shall have the meanings ascribed to such terms in the Motion to Disband and the Objections.

3. The Objections should be overruled for the following reasons:
- Neither section 1102 nor any other provision of the Bankruptcy Code *prohibits* the Court from disbanding the Committee. The Objections assert that the Bankruptcy Code is a straightjacket on the Court with respect to disbandment. As the U.S. Trustee and the Committee admit, however, and as authority in this District recognizes, the Bankruptcy Code is silent as to whether the Bankruptcy Court has authority to disband a committee. Silence does not equate to prohibition. Moreover, and as expressly determined by other courts, section 105 of the Bankruptcy Code provides ample authority for the Court to grant the Motion to Disband;
 - Patheon is not and cannot be a prepetition creditor of SIGA, and is not eligible to sit on the Committee. Maintaining a “committee of *creditors*” comprised of one member is in direct contravention of the Bankruptcy Code and the purpose of a creditors’ committee;
 - PharmAthene, which has controlled the Committee from its inception, has demonstrated that it is more than capable of monitoring the Debtor and the administration of this case. It should not be permitted to continue to use estate resources to fund its activities. Moreover, the ongoing chapter 11 plan negotiations are, in reality, with PharmAthene and will continue on a constructive basis in the absence of the Committee; and
 - The Committee’s concern over its right to appeal a disbandment order can be addressed at the appropriate time. The Committee’s veiled threat of an appeal has no relevance to the matter before the Court.

Misstatements in the Objections

4. As an initial matter, it is necessary to address and correct some blatant misstatements and misrepresentations in the Objections:
- a. SIGA never “undertook efforts to block the appointment of a committee.” Committee Objection ¶ 8. This is abundantly clear in SIGA’s counsel’s letter, dated September 29, 2014, to the U.S. Trustee which the Committee annexes to its Objection. Nowhere does that letter state that a committee should not be appointed. Rather, it states the Debtor’s view that *if* a committee is appointed, PharmAthene should not sit on the committee because of the years of pending litigation between PharmAthene and the Debtor and the fact that the primary issue in the case is the disposition of that litigation.
 - b. Catalent Pharma Solutions, LLC (“**Catalent**”) did not resign from the Committee when its prepetition claim was paid by SIGA pursuant to this Court’s Order Pursuant to 11 U.S.C. §§ 105(a) and 1107(a) Authorizing, But Not Directing, Debtor to Pay Reimbursable Prepetition Obligations to Certain Service Providers

(ECF No. 99) (the “**Reimbursement Order**”). Committee Objection ¶ 10. Rather, Catalent resigned from the Committee on October 13, 2014—six (6) days after it was appointed to the Committee; the Reimbursement Order was entered on October 28, 2014, two (2) weeks *after* Catalent already had resigned; and Catalent still holds a prepetition unsecured claim against the Debtor.

- c. Even if it were relevant to the Motion to Disband, the Committee categorically states without any proof or basis whatsoever that the Debtor’s filing of its motion to assume its contracts with BARDA “triggered Albemarle, at the time a member of the Committee . . . to file” its motion to compel the Debtor to assume or reject its executory contract. Committee Objection ¶ 12. There is no evidence anywhere to support this statement.
- d. The appeal of the PharmAthene litigation to the Delaware Supreme Court will not “take a year or longer.” Committee Objection ¶ 31. The appeal will be fully briefed as of today, and oral argument is expected in the summer, with a decision in the fall of this year.
- e. SIGA did not “resist[] the Committee’s efforts to investigate potentially valuable estate causes of action, prompting the Committee to file its Rule 2004 Motion.” Committee Objection ¶ 34. *First*, SIGA became aware the Committee was going to file a motion seeking discovery under Bankruptcy Rule 2004 the day before it was filed. *Second*, SIGA was completely surprised that the Committee would want to chill ongoing constructive chapter 11 plan negotiations by filing such a polarizing motion. *Third*, as demonstrated in the Debtor’s objection to the Committee’s Rule 2004 Motion, the Committee’s Bankruptcy Rule 2004 campaign is a fruitless exercise, would be “time consuming and expensive,” according to the Committee, and would be detrimental and prejudicial to all parties in interest. It is nothing more than a transparent leverage play that should not be countenanced.

5. Lastly, the allegations made by the U.S. Trustee and the Committee that “since the Petition Date, SIGA has engaged in what appears to be a concerted effort to undermine the membership of the Committee” and that “[t]hrough various *court orders*, SIGA has paid off the claims of two prior members of the Committee (causing them to resign from the Committee), and has paid the pre-petition claims of many other preferred creditors”—should have no bearing

on the Court's determination of the Motion to Disband.² Committee Objection ¶ 35 (emphasis added); U.S. Trustee Objection pp. 2, 5.

6. In addition to being completely false, these allegations can easily be dismissed. At the recent hearing where PharmAthene objected to the Debtor's assumption of the BARDA Contracts, PharmAthene raised the same issues. The Court quickly responded, noting that all prepetition claims paid by the Debtor and all contracts assumed by the Debtor were the subject of motions filed by the Debtor, hearings, and Court approval. All parties, including the U.S. Trustee and the Committee, had the right to object and be heard. They did not.

7. It is indeed ironic that the Committee and the U.S. Trustee accuse SIGA of acting improperly and engaging in a scheme to eliminate potential Committee members when, in fact, SIGA has used the tools of the Bankruptcy Code to assume contracts under section 365 of the Bankruptcy Code and to obtain other relief from the Court in order to maximize enterprise value as the Bankruptcy Code contemplates. Now, because SIGA has not sought the same relief with respect to its executory contract with Patheon, both the Committee and the U.S. Trustee are using these circumstances opportunistically to attempt to create a prepetition creditor to prolong the Committee's existence.

8. Bald and unfounded accusations, allegations of "unlawfulness," and strident and vituperative language are not a substitute for the undisputed facts, the applicable law, and sound legal reasoning, as set forth below.

² Notably, in connection with the Motion to Disband, the Committee recently served document requests and a Rule 30(b)(6) deposition notice on the Debtor. The discovery sought insinuates, without any basis whatsoever, that SIGA essentially engaged in fraudulent conduct to pay prepetition claims in violation of the provisions of the Bankruptcy Code and this Court's orders. Of course, this is not the case. This pointless exercise simply is more evidence of the Committee's utter disregard for the costs and expenses it is incurring and the costs and expenses it is causing the Debtor to incur, all at the expense of the Debtor's economic stakeholders.

The Court Has Authority to Disband the Committee

9. In asserting that the Court does not have the authority to disband the Committee, the Committee and the U.S. Trustee rely largely on *In re Caesars Entertainment Operating Co., Inc.*, 526 B.R. 265 (Bankr. N.D. Ill. 2015), and assertions that because section 1102 of the Bankruptcy Code is silent as to whether the Court has the power to disband the Committee, this must mean that Congress has unequivocally precluded the Bankruptcy Court from doing so. *Caesars*, however, (as well as *In re New Life Fellowship, Inc.*, 202 B.R. 994 (Bankr. W.D. Okla. 1996) also relied on by the Committee) are not controlling here and, as acknowledged, there is no provision in the Bankruptcy Code that prohibits a Bankruptcy Court from disbanding an official committee. In fact, in *In re Texaco Inc.*, 79 B.R. 560 (Bankr. S.D.N.Y. 1987), a case in this District, the Bankruptcy Court did disband an official committee.

10. Astonishingly, both the Committee and the U.S. Trustee fail to call to the Court's attention the recent decision in the City of Detroit bankruptcy case that squarely addressed the Bankruptcy Court's authority to disband an official committee of unsecured creditors, finding that such authority exists under section 105 of the Bankruptcy Code. *In re City of Detroit, Michigan*, 519 B.R. 673, 679-80 (Bankr. E.D. Mich. 2014).

11. In *Detroit*, a case under chapter 9, the Debtor filed a motion seeking an order disbanding the Official Committee of Unsecured Creditors appointed by the United States Trustee. Both the Official Committee and the United States Trustee objected, as here, on the basis that the Bankruptcy Court had no authority to disband an official committee.

12. In granting the relief and disbanding the official committee, the Bankruptcy Court relied on its broad authority under section 105 of the Bankruptcy Code:

[t]he Court is authorized to vacate the appointment of the Committee pursuant to 11 U.S.C. § 105

Under section 105, bankruptcy courts have broad equitable power. . . .

This authority exceeds the equitable authority available under traditional equity jurisprudence.

Id. at 679-80 (internal quotation marks omitted) (citations omitted).

13. In addition, in ruling that section 105 grants the Bankruptcy Court authority to disband the Committee, the Court in *Detroit* specifically addressed and rejected the same arguments and authority raised by the U.S. Trustee and the Committee here, that the Court's reliance on section 105 for authority to disband the Committee was inappropriate because to do so would be inconsistent with section 1102:

Nevertheless, [t]he bankruptcy court's broad equitable powers are . . . constrained to actions or determinations that are not inconsistent with the Bankruptcy Code.

The Court finds that vacating the appointment of the Committee is not inconsistent with the bankruptcy code. On this point, the Committee and the U.S. Trustee focus on the fact that the bankruptcy code explicitly grants to the court the authority to order that a committee of creditors not be appointed in cases involving a small business debtor, 11 U.S.C. § 1102(a)(3), and to review the composition of the committee, 11 U.S.C. § 1102(a)(4). They argue that these provisions evidence the outer bounds of a bankruptcy court's authority to review the U.S. Trustee's decision to appoint the Committee.

The difficulty with this roundabout argument is that nowhere does the bankruptcy code explicitly prohibit the bankruptcy court from disbanding an unsecured creditors' committee. Therefore, interpreting § 105 to authorize a bankruptcy court to do so is simply not inconsistent with any bankruptcy code provision. Accordingly, the Court concludes that it has the authority to disband the Committee if the Court, exercising its discretion, determines that doing so "is necessary or appropriate" to carry out the provisions of title 11. See 11 U.S.C. § 105(a).

Id. at 680 (internal quotation marks omitted) (emphasis added).

14. As stated above, the Committee and the U.S. Trustee both acknowledge that, as this Court has noted, section 1102 and the balance of the Bankruptcy Code are silent as to whether the Court has the authority to disband the Committee. *See In re Dewey & LeBoeuf LLP*, No. 12-12321 MG, 2012 WL 5985325, at *3 (Bankr. S.D.N.Y. Nov. 29, 2012); *Texaco Inc.*, 79 B.R. at 565. As recognized by the Bankruptcy Court in the *Detroit* case, this hardly warrants the leap made by the Committee and the U.S. Trustee that section 1102 *prohibits* the Court from doing so. Silence does not equate with preclusion. Indeed, if Congress wanted to deprive the Court of its authority and leave the U.S. Trustee as a complete free agent with no oversight, it easily could have done so. It did not.

There Cannot Be a Committee of One

15. As set forth in the Motion to Disband, the express statutory provisions are absolutely clear—section 1102 provides that “the United States Trustee shall appoint a committee of *creditors* holding unsecured *claims*.” 11 U.S.C. § 1102(a)(1) (emphasis added). A committee of unsecured creditors is just that—a committee of “creditors” with “claims” (both plural), not a committee of a “creditor.” Not only does the section heading use the plural term but the word “creditors” appears no less than eight (8) times in the body of the statutory section. According to the Committee and the U.S. Trustee, the Court should just ignore the plain words of the statute and maintain a creditor “committee” consisting of one entity. Notably, neither the Committee nor the U.S. Trustee has cited any authority or even referenced any case where there has been an official committee consisting of only one creditor.

16. The Committee’s reference to other sections of the Bankruptcy Code that mention specific numbers is irrelevant. Section 1102 is clear—“creditors” is plural—it cannot mean one creditor and reference to other sections cannot change this inescapable fact.

17. Recognizing the weakness of its statutory argument, the Committee asserts that because the appointment of a *creditors'* committee is mandatory, the appointment of a committee of one is authorized and appropriate. Committee Objection ¶ 28. SIGA agrees that section 1102 states that the "United States Trustee *shall* appoint a committee of *creditors* holding unsecured *claims*." The mandatory statutory language, however, does not override the other words of the statute nor in any way require the appointment of a one member committee if other qualified members cannot be found. In fact, there are many cases where committees are not appointed despite the mandatory language of section 1102(a).

18. The recent improper appointment of Patheon to the Committee does not moot the issue as the Objections contend. The incontrovertible facts clearly and conclusively demonstrate that Patheon cannot legitimately serve on the Committee:³

- Patheon is not a prepetition unsecured creditor of SIGA and *never* can be for the following reasons:
 - There are no outstanding prepetition or, for that matter, postpetition claims owing to Patheon. All prepetition claims were fully paid pursuant to this Court's Order authorizing SIGA to pay claims reimbursable by BARDA; and
 - No claims can arise under SIGA's contractual relationship with Patheon even in the remote event that it were rejected under section 365 of the Bankruptcy Code. The contract has broad termination provisions permitting termination for any reason and, in such event, the only amounts that could be payable to Patheon would be for outstanding services rendered that were unpaid as of the date of termination. Because all claims for prepetition services have been paid, the *only* possible claims that could arise as the result of termination or rejection would be for any unpaid postpetition services. By definition, any such claims would constitute costs and expenses of administration, not prepetition general unsecured claims.
- Services performed by Patheon for SIGA under the contract are fully reimbursable by BARDA; and

³ A copy of SIGA's contract with Patheon is annexed hereto as **Exhibit "A."**

- The likelihood that SIGA ever would seek to reject its contract with Patheon is virtually zero. What benefit could there possibly be? As stated, SIGA's obligations under the Patheon contract are reimbursed by BARDA. More importantly, Patheon is a long-standing provider that provides technical services integral to SIGA's performance under its contracts with BARDA. It would be highly disruptive and costly for SIGA to obtain a substitute provider on any timely basis because of BARDA's unique requirements as a government contractor including, among other things, the security and other clearances involved.

19. Neither the Committee nor the U.S. Trustee has disputed the foregoing facts other than by identifying Patheon as a "contingent" creditor, without any basis. The U.S. Trustee's unhelpful assertion in this regard that it "is not in the business of determining which claims are or are not allowable," citing to *In re JNL Funding Corp.*, 438 B.R. 356, 362 (Bankr. E.D.N.Y. 2010), misses the mark. U.S. Trustee Objection p. 6. First, *JNL Funding* involved disputed claims with a genuine issue as to liability. That is not the case here. Moreover, the *JNL Funding* Court noted that, in appointing a committee, the U.S. Trustee is "making an . . . assessment under Section 1102(a)(1) of who may hold *significant unsecured claims*" and "to populate that committee with *holders of significant claims*." *Id.* at 362-63 (emphasis added). Clearly, that has not occurred here with respect to Patheon.

20. In stark contrast, Patheon can have no prepetition claim, contingent or otherwise. Indeed, what the U.S. Trustee is suggesting is that it has the authority to put its head in the sand and to appoint any entity to a creditors' committee without engaging in the most fundamental amount of due diligence as to the underlying basis for its claim. This cannot be the law.⁴

⁴ SIGA is not seeking to "dictate which creditors may serve on the committee." U.S. Trustee Objection p. 5. Rather, it seeks to assure that the intent and purpose of section 1102 and the Bankruptcy Code is not undermined and estate resources wasted by having an entity appointed to a committee that is not a creditor merely to prolong the Committee's existence. With the U.S. Trustee's constant focus on professional fees and expenses in chapter 11 cases, it seems odd that the U.S. Trustee does not seem to share this concern.

21. Under the circumstances that exist here, to permit Patheon to remain on the Committee would constitute a complete perversion of the committee process.

**A Committee of One Creditor is Not Necessary
for the Efficient or Proper Administration of this Case**

22. The Committee asserts that maintaining its existence, even with PharmAthene as its only member, is necessary to provide “formal supervision” of the Debtor and to incentivize SIGA to emerge from chapter 11 on a prompt basis. Committee Objection ¶ 31. The Committee is wrong. The continued existence of the Committee will not facilitate the administration of this case or the maximization of value for the Debtor’s stakeholders, and the Committee is not necessary to the chapter 11 plan negotiation process now underway.

23. It has been abundantly clear since the Committee’s appointment that it has been dominated and controlled by PharmAthene. PharmAthene has a huge financial stake in the administration of SIGA’s chapter 11 case. To suggest that any effort to supervise the Debtor or to incentivize the Debtor to emerge from chapter 11 will vanish if the Committee is disbanded, ignores reality. This is particularly the case where PharmAthene believes that because of its Delaware court judgment it is effectively the owner of SIGA.

24. Moreover, in reality, the ongoing plan negotiations are between the Debtor and PharmAthene, as the only real creditor in interest. The Debtor’s counsel and PharmAthene’s counsel already have interacted directly in the plan negotiation process and, based on the economic and other interests at stake, these negotiations will continue in the same fashion. PharmAthene has demonstrated that it is more than capable of representing itself and does not need the auspices of the Committee to protect its rights.

25. Indeed, it is more likely that the administration of this case and the plan process would proceed more efficiently, economically, and expeditiously if the Motion to Disband were

granted and PharmAthene had to fund its own legal fees and expenses rather than free-ride on the resources of the Debtor's estate. In this regard, SIGA wholeheartedly agrees that in the absence of a Committee and its professionals being funded by the estate, the Committee's 2004 Motion never would have been filed. Committee Objection n. 17. Simply put, neither PharmAthene nor any other creditor itself would pay the substantial fees and expenses associated with this fruitless and admittedly "time consuming and expensive" mischief. *See* Committee's Motion to Retain Special Litigation Counsel (ECF No. 386) ¶ 11.

Conclusion

26. The Court should grant the Disbandment Motion and immediately disband the Committee.

WHEREFORE the Debtor respectfully requests that the Court overrule the Objections, enter an order granting the Disbandment Motion, and grant the Debtor such other and further relief as is just.

Dated: New York, New York
May 11, 2015

/s/ Stephen Karotkin
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Exhibit A

MASTER SERVICES AGREEMENT
with
SIGA Technologies, Inc.,

This Agreement is entered into and made effective as of the date of last signature, (the "Effective Date") by and between SIGA Technologies, Inc., a Delaware corporation with a place of business at 35 E. 62nd Street, New York, NY 10065, USA ("SIGA") and DSM Pharmaceuticals, Inc., a Delaware corporation having its principal offices at 5900 Martin Luther King Jr. Hwy, Greenville, NC 27834 ("Company") (each individually a "Party" and collectively, the "Parties").

1. Purpose and Scope. This Agreement sets forth the terms governing the provision by the Company of certain services related to the development of pharmaceutical drug products (each referred to individually as a "Product"), including the delivery of certain information and materials, to SIGA (hereinafter collectively the "Services"). All such Services shall be performed pursuant to one or more Statements of Work attached to this Agreement from time to time, an example of which is attached hereto. Each Statement of Work may be amended only by written agreement of the Parties. The initial Statement of Work will be titled Statement of Work #1 and any additional Statements of Work will be numbered in sequential order, and shall become a part of this Agreement as Exhibits (Exhibit A, Exhibit B, etc). Each Statement of Work will contain a description of the Services to be performed, including any information, written report or other materials to be delivered, the price to be paid by SIGA to Company for the Services broken down in such detail as agreed by the Parties, a schedule for the performance of the Services, any specialized equipment required to perform the Services, and such other terms and conditions that are consistent with this Agreement to which the Parties may agree. Each Statement of Work shall be binding only upon signing by both Parties, and shall not be effective unless it is executed by an authorized representative of each Party.
2. Reports. Unless otherwise provided in a Statement of Work, for each Service performed under this Agreement, Company shall deliver to SIGA a writing in English, in electronic or hard copy format, which describes the procedures carried out in each experiment and contains all other specific information required by the Statement of Work ("Report"). SIGA shall be the sole owner of any such Report, except that ownership of the content of each Report shall be governed by Section 6 hereinafter. Company shall keep SIGA reasonably informed of the status and progress of its performance of Services, which obligation shall continue through completion of each Service and delivery of any written information or Report required to be delivered under a Statement of Work or this Agreement. At SIGA's reasonable request, but not more than once during the course of the performance of Services under any Statement of Work, Company shall promptly provide to SIGA copies of all documentation in the Company's possession relating to the Services or shall permit SIGA to inspect and copy such documentation. Any additional request for documentation shall

be subject to Company's consent and SIGA's reimbursement of any direct costs incurred by Company in connection with the request.

3. Term and Termination. The term of this Agreement shall commence on the Effective Date and continue until the later of (i) the one-year anniversary of the Effective Date or (ii) the date that work under all Statements of Work issued hereunder have been completed, unless the Parties mutually agree to extend this Agreement. Notwithstanding the foregoing, this Agreement shall terminate on the date of signing of a Definitive Agreement (hereinafter defined), unless such Definitive Agreement expressly provides that this Agreement or any Statement of Work hereunder shall continue in force and effect until the Services are completed. Further, either Party may terminate this Agreement at any time upon thirty (30) days written notice to the other. Unless otherwise specifically set forth herein or agreed by the Parties, termination of this Agreement shall not result in the termination of any Statement of Work then in progress, and the terms of this Agreement shall apply to such Statement of Work. Either Party may terminate a particular Statement of Work, effective on the date of the Party's written notice to the other, (i) if the Services are not progressing according to the expectations of SIGA and Company and SIGA cannot agree on appropriate scope changes or additional financial costs associated with scope changes; or (iii) if Company is unable to perform the Services in a safe and effective way in accordance with applicable regulatory requirements. Upon termination of this Agreement or a Statement of Work, Company shall at SIGA's request, return all papers, records and other documents embodying SIGA Confidential Information (as defined herein), including without limitation all SIGA Material, and all embodiments of SIGA Know-How. SIGA shall pay Company for all Services completed by Company prior to or in connection with any such termination.
4. Payment for Services and Information. SIGA shall pay Company the total amount set forth in the applicable Statement of Work and Company shall invoice SIGA as set forth in the applicable Statement of Work. Any additional costs incurred by Company pursuant to this Agreement shall be invoiced monthly for actual costs incurred prior to the invoice date. Unless otherwise provided in the applicable Statement of Work, SIGA shall make payment for all invoices within thirty (30) days of receipt. SIGA and Company agree that for any Statement of Work relating exclusively to the lyophilization cycle optimization of ST-246, SIGA shall make payment for all invoices relating to such Statement(s) of Work within forty five (45) days of receipt. Overdue payments may in Company's discretion bear interest at the rate of one percent (1%) per month, pro-rated for any partial month, beginning with the day following the due date and continuing to the date of payment. Where a Statement of Work or other written agreement of the Parties obligates SIGA to pay for specialized equipment or tooling required for Company to perform the Services, SIGA shall separately pay Company, on an as-costs-are-incurred basis for Company's cost for such equipment or tooling required at Company's facility to perform the Services. In addition, any sales, use, consumption, or excise taxes of any taxing authority which are imposed upon the Services supplied hereunder shall be reimbursed to Company by SIGA.

Invoices shall be emailed to Katie Hicks at khicks@sigacom and to Roy Cysner at rcysner@sigacom. Hard copies of invoices shall be mailed to: SIGA Technologies, Inc. Attn. Katie Hicks, 4575 SW Research Way, STE 230, Corvallis, OR 97333.

5. Retained Ownership and Confidentiality. In connection with providing the Services, Company and SIGA may be given access to information that is the proprietary information of the other, including information contained in the Statement of Work, (hereinafter referred to as "Confidential Information"). SIGA Confidential Information shall include material including chemical compounds disclosed to Company for the purposes of performing the Services hereunder ("SIGA Material"). Company may not use SIGA Material in humans. Company Information may include commercial, financial and technical information, information relating to customers, suppliers, plant design and layout, equipment, production processes, data, databases and extracts therefrom, methods, personnel information, marketing and pricing information, and other concepts, and ideas reasonably necessary for Company to disclose to SIGA, or ascertainable by SIGA while SIGA is present at the Company's Facility, in connection with the performance by Company of the Services under a Statement of Work. Company shall not provide to SIGA any Confidential Information related to any of Company's proprietary technologies unless reasonably necessary to perform the Services, and where agreed to by SIGA in advance. Each Party may use any Confidential Information received hereunder only in connection with the Services pursuant to a Statement of Work, and may not use or exploit any Confidential Information received hereunder for any other purpose. The receiving party shall keep completely confidential and, except as provided for in this Section 5, shall not disclose or publish, and shall not transfer or deliver, to any third party without the prior written consent of the disclosing party, which it may withhold in its sole discretion, any Confidential Information of the disclosing party, any derivative, analog, modification or component thereof or any information relating thereto, including all documents and information generated by Company as a result of the Services performed pursuant to this Agreement. Each Party shall safeguard the other Party's Confidential Information with the same care as it protects its own confidential information from disclosure, but no less than reasonable care under the circumstances. The receiving party may disclose such Confidential Information solely to those individuals employed or retained by it with a "need to know" such information for purposes of this Agreement, provided that all such persons are informed in advance of the restrictions of this Agreement and agree to abide by them as if they were parties to this Agreement. Upon termination of this Agreement, at the disclosing party's direction and expense, the receiving party shall either return or destroy any Confidential Information in its possession in electronic or hard copy format. If requested by SIGA, Company shall also return to SIGA any and all unused SIGA material in Company's possession at the time of termination. These obligations of confidentiality and non-use shall continue during the term of this Agreement and for a period of five (5) years thereafter. This Agreement shall not restrict the receiving party's use or disclosure of Confidential Information to the extent that it

can be established by the receiving party that such Confidential Information: (a) was already known to the receiving party, other than under an obligation of confidentiality to the disclosing party; (b) was in the public domain at the time of its disclosure to the receiving party; (c) became part of the public domain after its disclosure and other than through any act or omission in breach of an agreement with or other confidentiality obligation to the disclosing party; (d) was subsequently lawfully disclosed to the receiving party by a third party with no obligation of confidentiality to the disclosing party (each of (a)-(d), a "Confidentiality Exception"). The receiving party agrees to advise the disclosing party of the applicability of any of any foregoing Confidentiality Exception for any Confidential Information as soon as the receiving party becomes aware of such applicability. The receiving party shall also be permitted to disclose any Confidential Information of the disclosing party if required to do so pursuant to the order of legal authorities having jurisdiction, provided that the receiving party shall promptly notify the disclosing party of such compelled disclosure and permit the disclosing party to attempt by appropriate legal means to limit such disclosure. SIGA shall be permitted to disclose any of Company's Confidential Information that is reasonably required for any regulatory filing seeking approval of a Product.

6. Intellectual Property. Subject to this Section 6, SIGA shall be entitled to Reports and copies of information generated by Company pursuant to each Statement of Work issued hereunder.

6.1 Company shall remain the owner of all technology owned by or licensed to Company as of the Effective Date of this Agreement or developed or acquired by or for Company other than as a result of the activities hereunder (including without limitation manufacturing processes) and all patent and other intellectual property rights therein (the "Company Pre-Existing IP"), and nothing in this Agreement shall transfer or assign any ownership to SIGA. SIGA shall remain the owner of all technology owned by or licensed to SIGA as of the Effective Date of this Agreement or developed or acquired by or for SIGA other than as a result of the activities hereunder (including without limitation the Product and its manufacture, formulation or use) and all patent and other intellectual property rights therein (the "SIGA Pre-Existing IP"), and nothing in this Agreement shall transfer or assign any ownership to Company.

6.2 Company shall not use any Company Pre-Existing IP in performing Services for SIGA without SIGA's prior written approval. In the event that SIGA authorizes Company to use its Pre-Existing IP in performing Services or a Statement of Work for SIGA, the Parties shall negotiate a further agreement regarding any restrictions, royalties, or other terms and conditions pertaining to SIGA's use of such Company Pre-Existing IP. As between the Parties, and unless otherwise agreed in writing, Company shall solely own all right, title and interest in and to all inventions and discoveries that consist of a modification or improvement to the Company

Pre-Existing IP that are conceived or reduced to practice by Company, SIGA, or jointly in connection with this Agreement together with all patent and other intellectual property rights covering or claiming such inventions and discoveries.

- 6.3 Except as otherwise provided in Section 6.1 and Section 6.2, Company shall solely own all right, title and interest in and to all inventions and discoveries by Company in connection with the performance of a Statement of Work that relate primarily to Company Pre-Existing IP ("DSM Invention"). SIGA shall be granted an exclusive, royalty free, perpetual, assignable worldwide license to use such DSM Invention or discovery in connection with the manufacturing, marketing, sale, distribution, export or import of the Product.
- 6.4 Except as provided in Sections 6.1, 6.2, or 6.3, SIGA shall own all other inventions and discoveries, no matter how conceived. To the extent that Company solely, or in combination with SIGA, creates or makes the invention or discovery, Company shall have a non-exclusive, royalty-free, non-transferable license to use such technology in connection with its business but only for products other than those that have a chemical composition and application substantially equivalent to that of the Product that is the subject of this Agreement in which the technology was developed.
- 6.5 Each Party hereby assigns to the other Party all of its right, title and Interest to the applicable invention, discovery and intellectual property rights in accordance with the foregoing.
- 6.6 Nothing contained herein shall grant any right, interest, title or license to Company in SIGA's Pre-Existing IP, or to SIGA in Company's Pre-Existing IP.
7. Performance Standard; Compliance with Law. Company shall perform the Services with professional skill and care consistent with industry standards. Company shall conduct the Services pursuant to a Statement of Work in accordance with all applicable laws, rules and regulations. Company represents and warrants to SIGA that it has the right to use any third party trade secrets, processes, methodologies or reagents used by the Company in generating any Information for or providing any Services to SIGA hereunder. Company hereby represents and warrants that it will not or has not employed or otherwise used in any capacity the services of any person debarred under Section 306(a) or (b) of the Federal Food, Drug, and Cosmetic Act in performing any Services hereunder. Company shall not without the written consent of SIGA, subcontract any services to be performed under a Statement of Work.
8. Liability. It is recognized and agreed by and between Company and SIGA, that

since the Services are of a developmental or research nature, there can be no guarantee that they will be successfully completed, or successfully completed within the contemplated time frame, despite Company's commercially reasonable efforts to do so. Company does not represent, warrant, or guarantee that its research results, or products produced therefrom, are merchantable or satisfactory for any particular purpose, and there are no warranties, expressed or implied, to such effect. SIGA hereby agrees to release, waive, and forever discharge any demands, claims, suits, or actions of any character against Company arising out of or in connection with SIGA's acceptance, reliance on, or use of such results and SIGA's only remedy for a breach of this Agreement by Company shall be for a refund of expenses paid to Company for the Services completed prior to the termination of this Agreement which did not comply with the requirements set forth in this Agreement. All other damages, including damages for delays, lost profits, lost business opportunity, or any special, indirect, incidental, or consequential damages and punitive damages are hereby expressly excluded.

9. Indemnity. Notwithstanding anything to the contrary in other provisions of this Agreement:

- a. Company shall defend, indemnify and hold harmless SIGA, its officers, employees, directors, affiliates, representatives, agents, successors and assigns from and against any and all demands, claims or actions of any character, liability, loss, damages, cost or expense (including attorneys' fees and expenses and costs of investigation) which any of them may hereafter incur, suffer or be required to pay as the result of any damage suffered or alleged to be suffered in connection with Company's acts or obligations under this Agreement, any Statement of Work, or the Services contemplated therein, including, without limitation, any damage alleged to be incurred by a third party (i) due to death or personal injury as the result of the gross negligence, or intentional misconduct of Company, or (ii) due to any claim that the Services provided by Company hereunder infringe a United States patent or any other proprietary right claimed by a third party.
- b. SIGA shall defend, indemnify and hold harmless Company, its officers, employees, directors, affiliates, representatives, agents, successors and assigns from and against any and all demands, claims or actions of any character, liability, loss, damages, cost or expense (including attorneys' fees and expenses and costs of investigation) which any of them may hereafter incur, suffer or be required to pay as the result of any damage suffered or alleged to be suffered in connection with SIGA's acts or obligations under this Agreement, any Statement of Work, or the Services contemplated therein, including, without limitation, any damage alleged to be incurred by a third party (i) due to death or personal injury as the result of the gross negligence or intentional misconduct of SIGA or (ii) due to any claim that any materials or processes provided, required or specified by

SIGA hereunder infringe a United States patent or any other proprietary right claimed by a third Party.

- c. Neither party shall be liable to the other party for penalties or liquidated damages or for special, indirect, consequential or incidental damages of any type or kind (including, without limitation, lost profits) regardless of whether any such losses or damages are characterized as arising from breach of contract, breach of warranty, tort, strict liability or otherwise, even if such party is advised of the possibility of such losses or damages, or if such losses or damages are foreseeable.
10. Public Announcements. Both Parties shall hold in confidence all information concerning this Agreement and the terms hereof and shall not make any public statement or announcement about it, nor issue news releases or advertising relating to the existence or implementation of this Agreement or the subject matter thereof without the prior written consent of the other Party, which consent may be withheld in either Party's sole discretion. Neither Party shall use the name, insignia, symbol, trademark, trade name or logotype of the other Party (or any abbreviation or adaptation thereof) without the prior written consent of such Party in each instance.
11. Independent Contractors. It is not the intent of Company and SIGA to form any partnership or joint venture, and nothing contained herein shall be construed to empower either Party to act as an agent for the other. The Parties agree that each of them shall, in relation to its obligations hereunder, be acting as an independent contractor.
12. Definitive Agreement. If SIGA desires to continue with the development of a Product during or after the completion of the Services hereunder, and it desires to do so using the services of the Company, the Parties will prepare and negotiate in good faith one or more definitive agreements (the "Definitive Agreements") as the Parties agree may be appropriate to any such further development. Definitive Agreements may include a Pharmaceutical Development Agreement, a Manufacturing and Supply Agreement, and/or a Quality Agreement. Until such Definitive Agreements are signed, Company shall continue the Services hereunder according to the terms of this Agreement and any Statements of Work issued hereunder. Nothing contained herein shall obligate SIGA to continue to develop a Product with services provided by the Company.
13. Assignment. Neither Party may assign this Agreement in whole or in part to any entity without the prior written consent of the other Party and provided that any such entity agrees to be bound by the terms of this Agreement and the assigning Party remains responsible for any and all liabilities or obligations which, at the time of the assignment, had already accrued to the non-assigning Party or which is attributable to a period prior to such assignment. Notwithstanding the foregoing, either Party may assign this Agreement to an affiliate or in connection

with a merger or acquisition. As used in this Agreement, affiliate shall mean any corporation or non-corporate entity which directly or indirectly controls, is controlled by, or is under common control with a Party. A corporation or non-corporate entity shall be regarded as in control of another corporation if it owns or directly or indirectly controls at least fifty percent (50%) of the voting stock of the other corporation; or (a) in the absence of the ownership of at least fifty percent (50%) of the voting stock of a corporation or (b) in the case of a non-corporate entity, the power to direct or cause the direction of the management and policies of such corporation or non-corporate entity, as applicable. This Agreement shall inure to the benefit of and be binding upon each Party and its successors and permitted assigns. Without limiting the generality of the foregoing, a merger, acquisition or change of control of either Party shall be deemed to be an assignment.

14. Contacts. All correspondence, Statements of Work, and Reports pertaining to or resulting from this Agreement should be directed to Tove' Bolken, SIGA Technologies, Inc., Vice President of Research Operations, in the case of SIGA, and Diane Lever, Sr. Account Director/Business Development, in the case of Company, in the case of Company, or such other person as the Parties may direct.
15. Changes to Statement of Work. Either Party shall have the right at any time, by written request of the Party's authorized representative, to request changes to all or any portion of any Statement of Work. If any such change causes a change in the cost of, or the time required for performance of a Statement of Work, an equitable adjustment shall be made in the price or delivery schedule or both.
16. Miscellaneous. This Agreement is to be governed by and construed under the laws of the State of Delaware. This Agreement (together with the Confidential Disclosure Agreement between the parties dated August 15, 2011) represents the entire agreement between the parties with respect to its subject matter, and supersedes any and all prior services agreements or understandings, whether oral or written concerning such subject matter. The headings of the paragraphs in this Agreement are included herein for convenience and shall not be considered in construing this Agreement.
17. Dispute Resolution. The Parties hereto agree that any dispute between them arising under or relating to the Agreement or the performance of the Parties hereunder shall be submitted to the federal or state courts in the State of Delaware.
18. Flow Down Terms. In the event that any Statement of Work is to be undertaken with funding from a grant or contract to SIGA from an agency of the U.S. Government, the terms set forth in Appendix A, which refer to certain clauses of the Federal Acquisition Regulation, agency supplements, policy directives or other terms and conditions ("Flow-Down Provisions") shall apply to this Agreement. The Parties acknowledge that such federal funding may require,

as a condition of award and continued eligibility for federal funding, that the Parties comply with additional contract provisions specific to the federal grant or contract. In the event that additional Flow-Down Provisions are included in SIGA's agreement with the U.S. Government after the date hereof, SIGA shall provide the Company with notice of and references to any such additional applicable Flow-Down Provisions and this Agreement shall be amended to include such additional Flow-Down Provisions that are accepted by Company. In the event that Company cannot comply with such additional Flow-Down Provisions or cannot comply without incurring costs, Company shall have the right to terminate this Agreement upon written notice to SIGA. Company has no obligation to comply with Flow-Down Provisions that are not specified in the relevant Statement of Work or required by law or regulation. If such Flow-Down Provisions require submission of cost or pricing data or other confidential business information for Company's performance of the Statement of Work, then SIGA shall notify Company of such requirements and Company shall provide directly to the Federal Government such data and information as is required for compliance with the Flow-Down Provisions. In the event of a conflict between the terms in Appendix A and the other provisions of this Agreement, the terms in Appendix A shall apply. Further, SIGA shall not be relieved of any obligations contained in this Agreement should it fail to comply with any Federal Acquisition Regulations required by its agreement with the U.S. Government or to otherwise comply with the terms of such agreement.

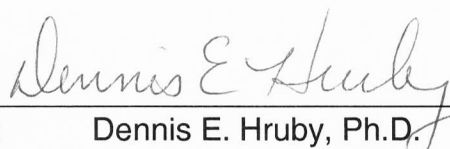
19. Force Majeure. Neither Party shall be held liable or responsible for any loss or damages resulting from any delay in its performance due hereunder (other than the payment of funds due hereunder) caused by the occurrence of any condition beyond the reasonable control of the affected Party including, without limitation, Acts of God, strikes or other labor disputes, war, riot, earthquake, tornado, hurricane, fire, civil disorder, explosion, accident, flood, sabotage, lack of or inability to obtain adequate fuel, power, materials, labor, containers, transportation, supplies or equipment; compliance with governmental requests (except as contemplated by the terms hereof), laws, rules, regulations, orders or actions; inability despite good faith efforts to renew operating permits or licenses from local, state or federal governmental authorities; breakage or failure of machinery or apparatus; national defense requirements; or supplier strike, lockout or injunction. In the event either Party is delayed or rendered unable to perform due to Force Majeure, the affected Party shall give prompt notice of the conditions and the expected duration to the other Party promptly after the occurrence of the cause relied upon, and upon the giving of such notice the obligations of the Party giving the notice will be suspended during the continuance of the Force Majeure.
20. Insurance. Each Party shall at all times maintain all necessary insurance coverage with sound and reputable independent insurers at commercially reasonable levels of coverage or shall be self insured having regard to the nature, type, scope and size of the business it conducts and all its respective activities and obligations under this Agreement. General liability coverage in the

amount of at least three (3) times annual revenues hereunder shall be maintained by each Party. Each Party shall, upon reasonable request of the other Party, produce satisfactory evidence that all insurance premiums have been paid and kept up to date and are kept in accordance with local insurance laws or regulations from time to time in force, or shall furnish appropriate certificates of insurance showing proof of coverage. The insurance coverage may be provided through a combination of primary, excess/umbrella or self-insured retention, and shall not serve to operate as a limitation on the recovery of any claim. Each Party shall include the other Party as a named insured on its policies of insurance, as the other Party's interests may be affected pursuant to this Agreement.

21. Disclosure/Development of Health Risk Data. SIGA agrees to disclose to Company any information which is or becomes available to SIGA regarding health risks which may be involved in the Services performed by Company related to any Product under a Statement of Work, including information regarding the specified active ingredients, excipients, and other components. Such information shall include, without limitation, OSHA required information, information regarding occupational exposure limits, toxicology studies and reports, and other health-related data. If reasonable industrial hygiene data is not available, Company and SIGA will cooperate to develop necessary and reasonable data as mutually agreed.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed below by duly authorized representatives.

SIGA Technologies, Inc.

BY:  DATE: 12 Jan 2012
NAME: Dennis E. Hruby, Ph.D.
TITLE: Chief Scientific Officer

DSM Pharmaceuticals, Inc.

BY:  DATE: 10 Jan 2012
NAME: Laura L. Parks, Ph.D.
TITLE: Sr. Vice President Marketing & Sales

[EXHIBIT EXAMPLE]

**Exhibit X
Statement of Work #X**

This Exhibit, details the services that Company will provide to SIGA. The services under this Exhibit shall be conducted under and subject to the terms and conditions of the Services Agreement between SIGA and Company, hereinafter ("SA").

Scope of Services

Insert Scope of Services

Payment Terms

Total charges for professional service fees and direct expenses will not exceed **\$XXX** without the prior written approval of SIGA. Upon the execution of this Exhibit, SIGA agrees to pay to Company according to the terms set forth in Paragraph 4 of the above-referenced SA.

Equipment

Term of this Exhibit

Insert anticipated start/end dates

The Scope of Services, Payment Terms and/or Term of this Exhibit may be amended upon the mutual written agreement of SIGA and Company.

SIGA Technologies, Inc.

BY: _____ DATE:_____

NAME: Dennis E. Hruby, Ph.D.
TITLE: Chief Scientific Officer

DSM Pharmaceuticals, Inc.

BY: _____ DATE:_____

NAME:_____

TITLE _____

Appendix A Flow-Down Provisions

Pursuant to Section 18 of the Agreement, the following Federal Acquisitions Regulation (FAR) clauses and Health and Human Services Acquisition Regulation (HHSAR) clauses are incorporated by reference as if in full text. By acceptance of this Agreement, Company and SIGA agree that the items supplied by Company to SIGA under this Agreement are Commercial Items as that term is defined in FAR 2.101. In all clauses listed herein, the terms "Government," "Contracting Officer" and "Contractor" shall be revised to suitably identify the contracting parties herein and affect the proper intent of the provision. "Subcontractor", however, shall mean "Company's Subcontractor," if any, under this subcontract. Notwithstanding the foregoing, in the clauses whose subject matter is intellectual property including but not limited to patents and rights in data, the terms "Government," "Contracting Officer" and equivalent phrases shall retain the meanings as set forth in FAR.

FAR and HHSAR Number (Date)

52.203-6	(Sept 2006)
52.203-12	(Sept 2006)
52.222-21	(Apr 1999)
52.222-26	(Mar 2007)
52.222-39	(Dec 2004)
52.222-50	(Aug 2007)

52.227-11	(Dec 2007)
52.227-14	(Dec 2007)
52.227-16	(June 1987)

52.249-6	(Sep 1996)
352.223-70	(Jan 2006)

52.222-35	(Sep 2006)
52.222.36	(June 1998)
52.222-37	(Sep 2006)
52.223-14	(Aug 2003)
52.227-1	(Dec 2007)
52.227-2	(Dec 2007)

**Exhibit A to the
Services Agreement
Dated 12 January 2012**

Statement of Work #1

This Exhibit, details the services that Company will provide to SIGA. The services under this Exhibit shall be conducted under and subject to the terms and conditions of the Services Agreement between SIGA and Company, hereinafter ("SA").

Scope of Services

The Scope of Services is applicable to **Phase I: Baseline Understanding of the Formulation** outlined in the **Proposal, Version 2**, entitled 'ST-246 Proposal for Lyophilization Cycle Optimization' submitted to SIGA on January 18, 2012 (see attachment A). The Scope of Services, Payment for Services and Information and/or Term of this Exhibit may be amended upon the mutual written agreement of SIGA and COMPANY.

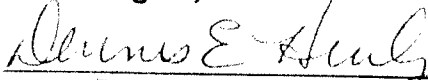
Payment Terms

Total charges for professional service fees and direct expenses will not exceed **\$31,200** without the prior written approval of SIGA. Upon the execution of this Exhibit, and unless the parties otherwise agree, Company shall invoice SIGA for Phase I Services at the time of Company's initiation of Phase I. SIGA agrees to pay to Company according to the terms set forth in Paragraph 4 of the above-referenced SA.

Term of this Exhibit


Services will commence upon execution of this Exhibit and will be completed by December 31, 2012.

SIGA Technologies, Inc.

BY: 
NAME: Dennis E. Hruby, Ph.D.
TITLE: Chief Scientific Officer

DATE: 30 Jan 2012

DSM Pharmaceuticals, Inc.

BY: 
NAME: David J. Parks
TITLE: Sr. V.P. Marketing & Sales

DATE: 13 Feb 2012



ST-246 Proposal for Lyophilization Cycle Optimization

Issued January 12, 2012
Version 2
for
SIGA Technologies, Inc.

Submitted By: **Diane Leven, Sr. Account Director/Business Development**

DSM Pharmaceuticals, Inc.
5900 Martin Luther King Jr. Highway
Greenville, NC 27834
www.dsmpharmaceuticalproducts.com

SIGA-ST-246
Proposal for Lyophilization Cycle Optimization
(250mg/50mL/25.0mL)&
Dosage/Vial Size/Fill Volume

Overview:

ST-246 is being considered for commercial production at the Sterile Products facility of DSM Pharmaceuticals. The drug substance is marketed in a 250 mg/vial dosage. The fill volume is 25.0mL into 50 mL vials at 10mg/mL.

The total freeze-drying cycle time for ST-246 is currently approximately 75 hours. SIGA is requesting a proposal for optimizing the cycle. In addition SIGA desires to shorten the reconstitution time of the lyophiles.

This outline provides the general rationale, method, and timeline for achieving such cycle optimization. It should be noted that as data and experimental results are gathered this approach may be in need of modification. This may include the need for additional experimental lyophilization runs.

The optimization method is divided into two distinct phases.

Phase I is primarily designed to establish a baseline of understanding. There are four specific areas of interests:

1. **Previous CMO's Development Work**
Rationale, Equipment Limitations, and Final Conclusions
2. **Confirmation of Previous CMO's Work**
Are conclusions valid for our equipment?
3. **Thermal Analysis of the Formulation**
What is the optimal product temperature as it relates to chamber pressure and successful lyophilization?
4. **Confirm the Baseline Lyo-cycle**
Execute SIGA's current Lyo-cycle in the 8 ft² development freeze dryer and confirm the results are in agreement with previous development work.

Note: *SIGA has indicated that it already has Thermal Analysis data. This data will be used to construct a temperature/pressure profile in V802.*

Phase II is designed to establish the operating range (design space) for freeze drying that will insure that the lyophiles meet all Critical Quality Attributes (CQAs).

Proposal for the Lyophilization Cycle Optimization of ST-246

Phase I: Baseline Understanding of the Formulation

Week 1:
Jan 15-22
\$4,500

Objective: Understand Previous Development Rationale

A. Review ST-246 Documentation:

- a. The rationale for the current formulation
- b. Freeze dryer engineering specifications and limitations
- c. Critical manufacturing process parameters
- d. Critical filling process parameters
- e. Make changes to project design accordingly
- f. Determine the final product's glass transition temperature (T_g)
- g. Determine the frozen formulation glass transition temperature (T_g)
- h. Determine the frozen formulation collapse temperature (T_c)

Note SIGA to provide f, g and h.

Week 2:
Jan 23-29
\$8,900

Objective: Protocol, Batch Execution Records, and Logistics

A. Receive Components and Establish Batch Execution Documents

- a. Create Manufacturing BER
- b. Create Filling BER
- c. Create Baseline FD cycle for V801/V802 Lyophilizers
- d. Configure V802 FD shelf package for In-Process sampling
 1. Test In-Process sampling of 50 cc vial in V802
- e. Review and confirm lyophile test methods
 1. Reconstitution
 2. Karl Fischer
 3. Assay
 4. 30 day Incubation of Samples/Accelerated Stability Test

Week 3:
Jan 30-Feb 5
\$8,900

Objective: Establish Lyo-Cycle Baseline

A. Execute 50 mL Lyo-run in V801 using current lyophilization cycle.

- 1. V801 Lyophilizer: Fully Loaded- 378 vials**
 - a. Establish baseline for Pressure Rise Testing
 - b. Evaluate baseline freeze dryer performance
 - c. Evaluate baseline relationship between shelf temperature, product temperature and chamber pressure
 - d. Evaluate baseline CQA's: shrinkage, cracking, collapse, uniformity
 - e. Establish and Evaluate Baseline testing (Assay, Moisture, Recon)
- 2. V802 Lyophilizer: One shelf In-process Sampling-126 vials**
 - a. Pull samples at various time points of Lyo-cycle
 - b. Test reconstitution times (different moisture levels, vacuum)
 - c. Place select samples in Non-GMP Stability incubator
 - d. Evaluate baseline CQA's: shrinkage, cracking, collapse, uniformity
 - e. Establish and Evaluate Baseline testing (Assay, Moisture, Recon)

Week 4:
Feb 6 -19
\$8,900

Objective: Design New Lyo-Cycle

- a. Author Summary Report for Weeks 1-3
- b. Rationale for Selecting New Lyo-Cycle's- Process Control Parameters
- c. Evaluate and Modify Phase II - Experimental Design Accordingly

Phase II: Lyo-Cycle Optimization and Robustness Testing
\$68,500

Once a new cycle has been designed, then the following design space will be executed to establish a proven acceptable operating range. The design space will establish upper and lower limits for shelf temperature and chamber pressure. It will test the lyophiles acceptability over the complete range to confirm the robustness of the new cycle.

Date	Run # 378 vials per Run	Shelf Temp Target °C	Chamber Pressure Microns	Vial Size mL	Prise Test Set Point µ/min
Feb 20 - Feb 26	1 FD V801	5	100	50	10/60
Feb 20 - Feb 26	2 FD V802	10	130	50	10/60
Feb 27 - Mar 4	3 FD V801	10	70	50	10/60
Feb 27 - Mar 4	4 FD V802	0	130	50	10/60
Mar 05 - Mar 11	5 FD V801	0	70	50	10/60
Mar 05 - Mar 11	6 FD V802	5	*200	50	10/60

*** P-max-** Maximum Pressure before reverting back to freeze phase.

Week 8:
Mar 12-19

Author Summary Report for Phase II**Grand Totals:**

Phase I = \$31,200

Phase II = \$68,500

Total = \$99,700

Send Lyo-Materials to:

DSM Pharmaceuticals Inc.
 Attention: Ronald Pate Bldg. 8
 5900 Martin Luther King Jr. Hwy.
 Greenville, NC 27834



Human BioArmor

PO Number 15875-011812

Net 30 Days

Purchase Order

To: DSM Pharamaceuticals
MLK Jr. Hwy
Greenville, NC 27834

From: SIGA Technologies, Inc
4575 SW Research Way-Suite 230
Corvallis OR 97333
Tel: 541-753-2000
Fax: 541-753-9999

Date: 1/23/12

Re: PO for Exhibit A Statement of Work #1

This is a Purchase Order in the amount of \$31,200 for Exhibit A Statement of Work #1. **This is a not to exceed amount. Please reference the purchase order number and contract number HHSO100201100023C-CLIN 0002-2.6.1 on the invoice in order for it to be paid.**

Please send invoices and refer any billing questions to me at the information above.

Thank you for all of your help putting this purchase together.

Katie Hicks

**Exhibit B to the
Services Agreement
Dated 12 January 2012**

Statement of Work #2

This Exhibit, details the services that Company will provide to SIGA. The services under this Exhibit shall be conducted under and subject to the terms and conditions of the Services Agreement between SIGA and Company, hereinafter ("SA").

Scope of Services

The Scope of Services is applicable to **Phase II: Lyo-Cycle Optimization and Robustness Testing** outlined in the **Proposal, Version 2**, entitled 'ST-246 Proposal for Lyophilization Cycle Optimization' submitted to SIGA on January 18, 2012 (see attachment A). The Scope of Services, Payment for Services and Information and/or Term of this Exhibit may be amended upon the mutual written agreement of SIGA and COMPANY.

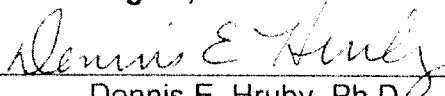
Payment Terms

Total charges for professional service fees and direct expenses will not exceed **\$68,500** without the prior written approval of SIGA. Upon the execution of this Exhibit, and unless the parties otherwise agree, Company shall invoice SIGA for Phase II Services at the time of Company's initiation of Phase II. SIGA agrees to pay to Company according to the terms set forth in Paragraph 4 of the above-referenced SA.

Term of this Exhibit

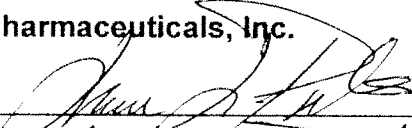
Services will commence upon execution of this Exhibit and will be completed by December 31, 2012.

SIGA Technologies, Inc.

BY: 
NAME: Dennis E. Hruby, Ph.D.
TITLE: Chief Scientific Officer

DATE: 30 Jan 2012

DSM Pharmaceuticals, Inc.

BY: 
NAME: Sarah L. Farkas
TITLE: Sr. V.P., Marketing & Sales

DATE: 13 Feb 2012



ST-246 Proposal for Lyophilization Cycle Optimization

**Issued January 18, 2012
Version 2
for
SIGA Technologies, Inc.**

Submitted By: Diane Lever, Sr. Account Director/Business Development

**DSM Pharmaceuticals, Inc.
5900 Martin Luther King Jr. Highway
Greenville, NC 27834
www.dsmpharmaceuticalproducts.com**

SIGA-ST-246
Proposal for Lyophilization Cycle Optimization
(250mg/50mL/25.0mL) &
Dosage/Vial Size/Fill Volume

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Proposal for the Lyophilization Cycle Optimization of ST-246

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- c. Critical manufacturing process parameters
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- e. Make changes to project design accordingly
- f. Determine the final product's glass transition temperature (T_g)
- g. Determine the frozen formulation glass transition temperature (T_g)
- h. Determine the frozen formulation collapse temperature (T_c)

Note SIGA to provide f, g and h.

Week 2:
Jan 23-29
\$8,900

Objective: Protocol, Batch Execution Records, and Logistics

A. Receive Components and Establish Batch Execution Documents

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 1. Reconstitution
 2. Karl Fischer
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 - d. Evaluate baseline CQA's: shrinkage, cracking, collapse, uniformity
 - e. Establish and Evaluate Baseline testing (Assay, Moisture, Recon)
- 2. V802 Lyophilizer: One shelf In-process Sampling-126 vials**
 - a. Pull samples at various time points of Lyo-cycle
 - b. Test reconstitution times (different moisture levels, vacuum)
 - c. Place select samples in Non-GMP Stability incubator
 - d. Evaluate baseline CQA's: shrinkage, cracking, collapse, uniformity
 - e. Establish and Evaluate Baseline testing (Assay, Moisture, Recon)

Week 4:
Feb 6 -19
\$8,900

Objective: Design New Lyo-Cycle

- a. Author Summary Report for Weeks 1-3
- b. Rationale for Selecting New Lyo-Cycle's- Process Control Parameters
- c. Evaluate and Modify Phase II - Experimental Design Accordingly

Phase II: Lyo-Cycle Optimization and Robustness Testing
\$68,500

Once a new cycle has been designed, then the following design space will be executed to establish a proven acceptable operating range. The design space will establish upper and lower limits for shelf temperature and chamber pressure. It will test the lyophiles acceptability over the complete range to confirm the robustness of the new cycle.

Date	Run # 378 vials per Run	Shelf Temp Target °C	Chamber Pressure Microns	Vial Size mL	Prise Test Set Point µ/min
Feb 20 - Feb 26	1 FD V801	5	100	50	10/60
Feb 20 - Feb 26	2 FD V802	10	130	50	10/60
Feb 27 - Mar 4	3 FD V801	10	70	50	10/60
Feb 27 - Mar 4	4 FD V802	0	130	50	10/60
Mar 05 - Mar 11	5 FD V801	0	70	50	10/60
Mar 05 - Mar 11	6 FD V802	5	*200	50	10/60

* **P-max-** Maximum Pressure before reverting back to freeze phase.

Week 8:
Mar 12-19
Author Summary Report for Phase II

Grand Totals:

Phase I = \$31,200

Phase II = \$68,500

Total = \$99,700

Send Lyo-Materials to:

DSM Pharmaceuticals Inc.
 Attention: Ronald Pate Bldg. 8
 5900 Martin Luther King Jr. Hwy.
 Greenville, NC 27834



Human BioArmor

PO Number 15876-011812

Net 30 Days

Purchase Order

To: DSM Pharamaceuticals
MLK Jr. Hwy
Greenville, NC 27834

From: SIGA Technologies, Inc
4575 SW Research Way-Suite 230
Corvallis OR 97333
Tel: 541-753-2000
Fax: 541-753-9999

Date: 1/23/12

Re: PO for Exhibit B Statement of Work #1

This is a Purchase Order in the amount of \$68,500 for Exhibit B Statement of Work #1. **This is a not to exceed amount. Please reference the purchase order number and contract number HHSO100201100023C-CLIN 0002-2.6.1 on the invoice in order for it to be paid.**

Please send invoices and refer any billing questions to me at the information above.

Thank you for all of your help putting this purchase together.

Katie Hicks

**Amendment 1 to Exhibit B to the
Services Agreement
Dated 12 January 2012**

Statement of Work #2

This Amendment 1 hereby modifies and is made an integral part of Statement of Work #2 ("SOW #2") between SIGA Technologies, Inc. ("SIGA") and DSM Pharmaceuticals, Inc. ("Company"), which was entered into pursuant to the Master Services Agreement between SIGA and Company dated January 12, 2012 ("SA").

Under and subject to the terms and conditions of the SA, SIGA and Company wish to amend and revise the Term for the completion of Services set forth in SOW #2 as set forth below.

SIGA and Company therefore agree as follows:

1. **Revised Term:** Upon full execution of this Amendment 1, the Term for the completion of the Services set forth in SOW #2 shall be extended for an additional 2 months. **All deliverables associated with the Scope of Services described in SOW #2 shall be completed by February 28, 2013.**

This Amendment 1 is issued pursuant to and, upon its full execution by SIGA and Company, shall become incorporated into SOW #2, which is incorporated into the SA.

The foregoing is the complete and final expression of the agreement between SIGA and Company to modify SOW #2 with respect to the Term for completion of the Services and cannot be modified, except by a writing signed by duly authorized representatives of both SIGA and Company.

By signing below, the authorized parties agree to the terms of this Amendment 1, effective as of the date of last signature below.

SIGA Technologies, Inc.

BY: Dennis E. Hruby

NAME: Dennis E. Hruby, Ph.D.

TITLE: Chief Scientific Officer

DATE: 04 Jan 2013

DSM Pharmaceuticals, Inc.

BY: Lawrence Thomas

NAME: Lawrence Thomas

TITLE: V.P. Marketing & Sales

DATE: 11 Jan 2013

**Exhibit C to the
Services Agreement
Dated 12 January 2012**

Statement of Work #3

This Exhibit details the services that Company will provide to SIGA. The services under this Exhibit shall be conducted under and subject to the terms and conditions of the Services Agreement between SIGA and Company, hereinafter ("SA").

Scope of Services

The Scope of Services is applicable to **Analytical Services** as presented in **ST-246 Clinical Batch Proposal, Version 3**, dated **27 February 2012** (see attachment A).

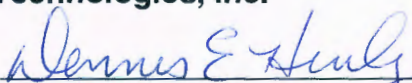
Payment Terms

Total charges for professional service fees and direct expenses will not exceed **\$188,300**. Upon the execution of this Exhibit, and unless the parties otherwise agree, Company shall invoice SIGA for **Analytical Services** at the time of Company's initiation of **Analytical Services**. SIGA agrees to pay to Company according to the terms set forth in Paragraph 4 of the above-referenced SA.

Term of this Exhibit

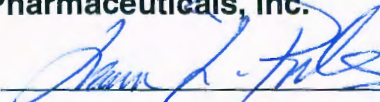
Services will commence upon execution of this Exhibit and will be completed by December 31, 2012.

SIGA Technologies, Inc.

BY: 
NAME: Dennis E. Hruby, Ph.D.
TITLE: Chief Scientific Officer

DATE: 22 Mar 2012

DSM Pharmaceuticals, Inc.

BY: 
NAME: Laura L. Parks
TITLE: Sr. VP Marketing & Sales

DATE: 9 Mar 2012



ST-246 Clinical Batch Proposal

**Issued February 27, 2012
Version 3
for
SIGA Technologies, Inc.**

**Submitted By:
Diane Lever, Sr. Account Director/Business Development**

DSM Pharmaceuticals, Inc.
5900 Martin Luther King Jr. Highway
Greenville, NC 27834
www.dsmpharmaceuticalproducts.com

SIGA-ST-246

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- 1.3 Terms of Supply

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- 2.1 Standard Project Assumptions
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Attachments

- Attachment 1: Capital
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Section 1: Executive Summary

1.1 Introduction

DSM Pharmaceuticals Inc. (DPI) is a leading provider of product Development, Manufacturing and Packaging services to global Pharmaceutical & Biotechnology companies. Through continuous Investment and Innovation, and with a commitment to Quality and Security of Supply, DPI strives to be the preferred partner of choice for the production of sterile & solid dosage forms. Delivering outstanding service & value to our customers, combined with our experience, relevant expertise and state-of-the-art equipment, makes us uniquely qualified to support product success.

DPI Delivers **Total Value** to its Customers:

- A **Sustainable** Business Partner
 - 100 Year Legacy of Royal DSM N.V.
 - World Leader on the Dow Jones Sustainability Index
 - Solid, Independent Financial Position
- A **Compelling Facility**
 - 1.5MM square feet over 640 acres
 - All service offerings based at one site
 - DSM capital investment of \$176MM since 2001
- An **Unparalleled Level of Experience**
 - Continuous operations in Greenville, NC for 40 years
 - Development, Manufacturing & Packaging services
 - Average staff tenure of 14 years
 - Repeatedly launch 10 or more new products annually
- **Premium Quality** Systems & Processes
 - Fully-integrated, computerized systems such as SAP, Documentum and Trackwise
 - Proprietary, oracle-based software system called iMost, for planning, scheduling and as a data hub, offering complete visibility into production status
- Demonstrated **Regulatory Excellence**
 - Extraordinary international agency audit history
 - More than 90% of PAIs waived since 2007
- **DEA Licensed** Facility
 - Licensed to manufacture CII-CV products

DSM Pharmaceuticals, Inc. appreciates the opportunity to propose clinical trial material (CTM) pricing to **SIGA Technologies, Inc.** for **ST-246**, and looks forward to further discussions to ensure we fully address your team's specific needs. We are confident that DPI offers unique advantages, making us the best CMO option. DPI's leadership position in the CMO sector is driven by collaborative partnerships, with the goal of mutual success.

DSM Pharmaceuticals, Inc. wishes to thank SIGA Technologies, Inc. for their consideration of our experience, expertise and Commitment to Excellence.

1.2 Proposal Summary

This proposal is focused on providing pricing for early phase clinical lyophilized ST-246 product utilizing a container closure system from DSM inventory, but it is not qualified on DSM's CTM line for SIGA Technologies, Inc.

1.3 Terms of Supply

1.3.1 CTM Price

Batch Type	Batch Size Vials	Per Batch Price	Tiers
ST-246 (50mL vial) CTM	~900	\$102,000	1 -2 CTM batches
ST-246 (50mL vial) CTM	~900	\$96,000	3-4 CTM batches
ST-246 (50mL vial) CTM	~900	\$89,000	> 4 CTM batches

- Price includes manufacturing, filling and bulk packaging into shippers.
- The following testing and QA release is included in price above:
Appearance, Water, Reconstitution time/appearance of solution, pH, Assay/Related Substances by HPLC, Hydrazine, Total Impurities, Particulate Matter, Osmolality, PFB, Sterility, and BET. Assumes DSM will ship samples to SIGA for contract testing of XRPD and SG1Diacid.
- Price does not include the active ingredient or Kleptose, to be provided by SIGA Technologies, Inc.
- Assumes a 25mL fill volume.
- Assumes lyophilization cycle is 75 hours.
- The container/closure to be used is a 50cc vial within DSM inventory. This vial and stopper requires validation on the CTM Line. DSM component item numbers: 50cc vial # 400015, 20mm stopper #005677 and Overseal # 013329.
- Assumes product does not require nude vial labeling.
- Rescheduling fee of \$10,000 will be charged for changes within the 30-day firm zone. A CTM agreement that also contains quality terms will be required prior to manufacture of CTM batches.

CTM Transfer Services and Activities

Description	Pricing
Project Management Support Analytical Services -Develop and Validate BET, Bioburden and Sterility Methods -Analytical method transfers: <u>Lyophilized Product:</u> <ul style="list-style-type: none"> Develop and Validate Water Content by KF. Validate and transfer Assay and Related Substances (SG2, 4TFMBA, ST-246 Exo Isomer, Impurity A, SG1 hydrazide) by HPLC. Trial alternative detection methods/techniques for SG1 Diacid Validate and transfer Hydrazine Verify Appearance of Lyophilized vial, Reconstitution time/Appearance of solution, pH, Particulate matter, Osmolality <u>Diluted Product:</u> <ul style="list-style-type: none"> Validate and transfer Assay and Related substances for Diluted sample. Validate and transfer Hydrazine for diluted sample. -Set up Analytical standard for the API and Product -Set up Analytical standard for Product to support stability testing -Assumes Appearance and ID on API and Kleptose.	 \$188,300
Validation Services -Validation CTM Line Assessment and Assessment Summary -Vial Washing Validation -Vial Depyrogenation Validation -Stopper Validation	 \$29,300
Water Batch (1) batch is required to test components and fill volume on the CTM line. (Siga requested to use Kleptose in this run, a non-issue per Lee Briley)	 \$47,600
Media Fills (3) media fills are required due to the new largest vial on the CTM line. (\$78,700 per media fill)	 \$236,100
Total:	\$501,300
ID test for final packaged CTM samples. (Optional)	\$2,400 per sample (Optional)

Capital Estimate: \$28,490 See attachment #1 for additional information.

Stability Estimate: \$111,800

Study	Price
One CTM batch on stability	\$111,800

1. Testing based on ICH guidelines.
2. See Attachment #2 for stability protocols and time point pricing.

Section 2: Project Strategy

2.1 Project Scope

This project is intended to execute the clinical manufacturing transfer of ST-246 for SIGA to the CTM line in Steriles North. DSM will supply CTM product to SIGA. The strategy for executing this project is as follows:

SIGA's ST-246 is an aseptically filled, lyophilized product in final dosage form. The product is intended for distribution in US clinical trials. The project requires at minimum the scope of work outlined in this proposal to qualify DSM as a site of manufacture for ST-246 CTM material.

The project's scope involves manufacturing, filling, and release of ST-246 CTM product and is therefore developmental in nature. As such, issues and unexpected outcomes are anticipated for which ongoing technical support by DSM may be required. Any unanticipated technical support is out of scope for this proposal.

In all aspects of this project, DSM is responsible for adhering to appropriate GMPs and sound defensible development or transfer plans which will be acceptable, in DSM's opinion, to current regulatory expectations.

2.2 CTM Strategy

2.2.1 Scope/ Contract Finalization

Following proposal approval, a CTM agreement that also contains quality terms will be approved by both organizations. After the CTM agreement is in place, the project will be initiated. Payment terms will be 14 days from invoice date.

2.2.2 Initial Process Feasibility/Transfer Activities

The CTM area Technical Representative will review the technical documents submitted by SIGA for the manufacture, filling and testing of ST-246. Documents to be provided by SIGA should include formula and manufacturing instructions/batch record, API/BDS and product storage requirements.

Analytical services include:

- Set up Analytical standard for the API, Kleptose and Product
- Develop and Validate BET, Bioburden and Sterility Methods
- Assumes Appearance and ID on API and Kleptose.

Analytical method transfers:

Lyophilized Product:

- Develop and Validate Water Content by KF.
- Validate and transfer Assay and Related Substances (SG2, 4TFMBA, ST-246 Exo Isomer, Impurity A, SG1 hydrazide) by HPLC.
- Trial alternative detection methods/techniques for SG1 Diacid
- Validate and transfer Hydrazine
- Verify Appearance of Lyophilized vial, Reconstitution time/Appearance of solution, pH, Particulate matter and Osmolality.

Diluted Product:

- Validate and transfer Assay and Related substances for Diluted sample.
- Validate and transfer Hydrazine for diluted sample.

The following testing and QA release is included in batch pricing:
Appearance, Water, Reconstitution time/appearance of solution, pH,
Assay/Related Substances by HPLC, Hydrazine, Total Impurities,
Particulate Matter, Osmolality, PFB, Sterility, and BET.

**Assumes DSM will ship samples to SIGA for contract testing of
XRPD and SG1 Diacid.**

2.2.3 CTM Services

CTM Batch – Multiple CTM batches are included in this proposal. All
in process and finished product testing will be required.

2.2.4 Validation Services

Validation Services include a CTM Line Assessment and Assessment
Summary.

Procedures for cleaning will be TOC for any equipment that is not
disposable utilizing the DSM cleaning model. All filler product contact
equipment is disposable.

2.2.5 Regulatory Services

DSM regulatory support activities are considered optional and are out
of the scope of this proposal.

2.2.6 DSM Quality Assurance

DSM's Quality Assurance department will act as a compliance
consultant and provide Quality oversight for adherence to regulatory
requirements. This will include but not limited to the following:
Documentation, Validation, and Investigations.

SIGA understands that DSM has considerable regulatory and
compliance responsibility associated with this project. In all aspects of
this project, DSM is responsible for adhering to appropriate GMPs and
sound defensible development plans which will be acceptable, in
DSM's opinion, to current regulatory expectations. DSM will not
knowingly execute (or bypass) activities which are inconsistent with

the above or which will jeopardize DSM's regulatory status. At a minimum DSM's applicable Quality Systems must be met.

2.3 Standard Project Assumptions

2.3.1 General Assumptions

1. Project requires completion of a MSDS and assessment of Safety issues, potential environmental concerns, and waste disposal procedures, as appropriate, for this project. This proposal assumes the Chemical Health Protection rating is a **CAT3** or less.
2. The API and excipients will be provided by the customer unless they are DSM current standard materials.
3. Customer will provide sufficient quantities of material for qualification of the BET and Sterility testing to be performed at DSM.
4. All materials supplied by SIGA Technologies, Inc. will arrive at DSM with appropriate documentation to be received into DSM's inventory, a certificate of analysis, certificate of compliance and chain of custody.
5. Standard DSM Documentation will be used for the filling process using the customer's critical parameters and process.
6. Storage condition of API and finished product will be controlled room temperature with ambient humidity.
7. A double sterile filtration will be performed.
8. Fill weight checks are part of the standard DSM process.
9. Inspection of the vials will include inspection for container closure and foreign matter (no product or cosmetic inspection). No retain samples will be taken or held at DSM.
10. Batch records review will be performed by DSM before QA release of the CTM batch. However upon request, product may be shipped under conditional status.
11. All unused material supplied by the customer will be returned or destroyed within 90 days of production if no additional demand is required.
12. Shipping of product, product samples, and documentation will be freight collect FOB Greenville. DSM will tender the materials to an approved carrier.

2.3.2 Optional Services Upon Request

- Regulatory Affairs documentation support.

2.3.3 Excluded materials or activities

Controlled or Cytotoxic substances are excluded materials from this production area.

1. DSM does not provide CTM labeling or final packaging at this time.
2. Phase III services are available and manufactured on commercial equipment.
3. Temperature controlled processing is not available on this equipment. Temperature controlled storage of API and finished product is available for specific temperature ranges.

2.4 Contacts Listing

Primary DSM contacts for this proposal are as follows:

Table 1: Contacts

Name	Phone number	Role	E-mail address
Diane Lever	510-524-2852	Sr. Account Director/Business Development	Diane.Lever@DSM.com
Lee Briley	252-707-7230	CTM Manager-Technical Lead	Lee.Briley@DSM.com
Jennifer Adams	252-707-2049	Business Services	Jennifer.Adams@DSM.com

Attachment 1: Capital Estimate

SIGA Technologies, Inc. (ST-246) Capital Estimate for CTM Line - North	
DESCRIPTION	BUDGET
50 ml vial size 20mm stopper, 25 ml fill - Lyo product	AMOUNT
EQUIPMENT	
Washer change parts (50 ml vial)	8,000
Misc. Tubing & Fittings and instruments	5,000
Filler change parts (50 ml vial)	8,000
FREIGHT	700
TAXES	700
CRAFTS	
Production mechanic	1,500
ENGINEERING	2,000
Subtotal	25,900
CONTINGENCY @ 10%	2,590
Total	\$28,490

Change parts have ~6 to 8 week leadtime.

Attachment 2: – Stability Protocols – (see next page)

Siga Technologies

ST-246 250 mg/vial

Package Presentation: 50 mL vial

One Storage Orientation

One CTM batch placed on stability (one stability study)

Study Attributes	Protocol Code
Physical Exam (Lyo Product Appearance)	A
Physical Exam (Reconstituted Product Appearance)	
Active Potency (Complex HPLC Assay)	
Related Substances/Impurities (Same Complex HPLC Assay, no addn'l stds)	
Hydrazine (Complex HPLC Assay)	
pH after reconstitution	
Dissolution/Reconstitution Time	
Moisture Content (KF)	B
XRPD	C
Particulate Matter (HIAC)	
Sterility	D
Bacterial Endotoxin (Gel Clot LAL)	
Dilution Testing: Active Potency (Complex HPLC Assay)	
Dilution Testing: Related Substances/Impurities (Same Complex HPLC Assay, no addn'l stds)	
Dilution Testing: Hydrazine (Different Complex HPLC Assay)	

Study Activities and Use Fees

Thermal Chamber Use Fee (for 1 basket of samples per storage condition)	X
Sample labeling (for Sterile products)	
Stability framework, protocol, and database creation	
SLIM Database Reports	Y

Storage Conditions and Activities	Intervals in Months										Total
	0	1	3	6	9	12	18	24	36	48	
Administrative	XY	Y	Y	Y	Y	Y	Y	Y	Y	Y	
40C/75%RH	A,B,C,D ⁽¹⁾	A	A	A,B,C,D							
25C/60%RH		A	A	A,B,C	A	A,B,C,D	A,B	A,B	A	A	
5C ⁽²⁾		A	A	A,B,C	A	A,B,C,D	A,B	A,B	A	A	

⁽¹⁾ Assumed that Product Release Data will be used for the initial (T0)

Price per Time point: \$ 10,500 \$ 9,700 \$ 9,700 \$ 18,900 \$ 8,300 \$ 18,900 \$ 9,600 \$ 9,600 \$ 8,300 \$ 8,300 \$ 111,800

Assumptions:

- 1) Analytical activities include the cost of reasonable and customary expendables associated with performing test methods, such as USP reference standards, solvents, and common HPLC columns, etc. However, some analyses may utilize especially numerous, particularly costly, or short-lived expendables, including limitedly available or expensive reference standards/markers as well as specialized, fragile, or short-lived HPLC columns, and other such "uncustomary" items. These limitedly available or atypically costly analytical items are not included in the analytical costs for this project and will either be provided by the client or billed to the client incrementally to the proposal price.
- 2) Assumed DSM has all required equipment and expertise to perform required tests (as listed in the bid).
- 3) Assumed that Product Release Data would be used for the initial (T0) timepoint.
- 4) Assumed assay and related substances are determined from the same HPLC analysis.
- 5) The sample allocations provided by Siga are not sufficient to support these studies.
- 6) Hydrazine is determined from a different HPLC analysis.
- 7) The dilution study includes the following tests: Assay and Related Substances and Hydrazine.

**Amendment 1 to Exhibit C to the
Services Agreement
Dated 12 January 2012**

Statement of Work #3

This Amendment 1 hereby modifies and is made an integral part of Statement of Work #3 ("SOW #3") between SIGA Technologies, Inc. ("SIGA") and DSM Pharmaceuticals, Inc. ("Company"), which was entered into pursuant to the Master Services Agreement between SIGA and Company dated January 12, 2012 ("SA").

Under and subject to the terms and conditions of the SA, SIGA and Company wish to amend and revise the scope of the services set forth in SOW #3 as set forth below.

SIGA and Company agree as follows:

1. Revised Scope of Services

The Scope of Services is applicable to **CTM Transfer Services** including **Analytical Services, Validation Services, Kleptose Release Testing and Kleptose Set-up Activities** and is revised as presented in **ST-246 Clinical Batch Proposal, Version 8**, dated **20 July 2012** attached hereto as Schedule A.

2. Fees and Payment Terms

Total charges for professional service fees and direct expenses will not exceed **\$202,900**. Upon the full execution of this Amendment 1, and unless the parties otherwise agree, Company shall invoice SIGA on a monthly basis for work performed as it relates to the Revised Scope of Services. SIGA agrees to pay to Company according to the terms set forth in Paragraph 4 of the above-referenced SA.

Term

Services will commence upon full execution of this Amendment 1 and will be completed by December 31, 2012.

This Amendment 1 is issued pursuant to and, upon its full execution by SIGA and Company, shall become incorporated into SOW #3, which is incorporated into the SA.

The foregoing is the complete and final expression of the agreement between SIGA and Company to modify SOW #3 with respect to the Revised Scope of Services and cannot be modified, except by a writing signed by duly authorized representatives of both SIGA and Company.

By signing below, the authorized parties agree to the terms of this Amendment 1, effective as of the date of last signature below.

Page 2 of 22

SIGA Technologies, Inc.

BY: Dennis E. Hruby DATE: 30 Jul 2012
NAME: Dennis E. Hruby, Ph.D.
TITLE: Chief Scientific Officer

DSM Pharmaceuticals, Inc.

BY: Jaura F. Port DATE: 6 Sep 2012
NAME: Jaura F. Port
TITLE: President & Business Unit Director

SCHEDULE A



ST-246 Clinical Batch Proposal

**Issued July 20, 2012
Version 8
for
SIGA Technologies, Inc.**

**Submitted By:
Diane Lever, Sr. Account Director/Business Development**

DSM Pharmaceuticals, Inc.
5900 Martin Luther King Jr. Highway
Greenville, NC 27834
www.dsmpharmaceuticalproducts.com

SIGA-ST-246

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- 1.1 Introduction
- 1.2 Proposal Summary
- 1.3 Terms of Supply

Section 2: Project Strategy

- 2.1 Standard Project Assumptions
- 2.2 Contacts Listing

Attachments

- Attachment 1: Capital
- Attachment 2: Stability

Section 1: Executive Summary

1.1 Introduction

DSM Pharmaceuticals Inc. (DPI) is a leading provider of product Development, Manufacturing and Packaging services to global Pharmaceutical & Biotechnology companies. Through continuous Investment and Innovation, and with a commitment to Quality and Security of Supply, DPI strives to be the preferred partner of choice for the production of sterile & solid dosage forms. Delivering outstanding service & value to our customers, combined with our experience, relevant expertise and state-of-the-art equipment, makes us uniquely qualified to support product success.

DPI Delivers **Total Value** to its Customers:

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 - Solid, Independent Financial Position
- A **Compelling Facility**
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 - Average staff tenure of 14 years
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- Demonstrated **Regulatory Excellence**
 - Extraordinary international agency audit history
 - More than 90% of PAIs waived since 2007
- **DEA Licensed** Facility
 - Licensed to manufacture CII-CV products

DSM Pharmaceuticals, Inc. appreciates the opportunity to propose clinical trial material (CTM) pricing to **SIGA Technologies, Inc.** for **ST-246**, and looks forward to further discussions to ensure we fully address your team's specific needs. We are confident that DPI offers unique advantages, making us the best CMO option. DPI's leadership position in the CMO sector is driven by collaborative partnerships, with the goal of mutual success.

DSM Pharmaceuticals, Inc. wishes to thank SIGA Technologies, Inc. for their consideration of our experience, expertise and Commitment to Excellence.

1.2 Proposal Summary

This proposal is focused on providing pricing for early phase clinical liquid ST-246 product utilizing a 30cc qualified container closure system on DSM's CTM line for SIGA Technologies, Inc.

1.3 Terms of Supply

1.3.1 CTM Price

Batch Type	Batch Size Vials	Per Batch Price	Tiers
ST-246 (30mL vial) CTM	~1,800	\$80,000	1-2 CTM batches
ST-246 (30mL vial) CTM	~1,800	\$75,000	3-4 CTM batches
ST-246 (30mL vial) CTM	~1,800	\$70,000	> 4 CTM batches

1. Price includes manufacturing, filling and bulk packaging into shippers.
2. The following testing and QA release is included in price above:
Appearance, pH, Assay/Related Substances by HPLC, Hydrazine, Total Impurities, Particulate Matter, Osmolality, PFB, Sterility, and BET.
Assumes DSM will ship samples to Ricerca for contract testing of SG1Diacid.
3. Price does not include the active ingredient or Kleptose, to be provided by SIGA Technologies, Inc.
4. Assumes a 22mL fill volume.
5. The container/closure to be used is a 30cc vial within DSM inventory. This vial and stopper is qualified on the CTM Line. DSM component item numbers: 30cc vial #321649, 20mm Stopper # 005305, Cap # 013329.
6. Assumes product does not require nude vial labeling.
7. Rescheduling fee of \$10,000 will be charged for changes within the 30-day firm zone. A CTM agreement that also contains quality terms will be required prior to manufacture of CTM batches.

CTM Transfer Services and Activities

Description	Pricing
Project Management Support	
Analytical Services	\$148,900
-Develop and validate BET, Bioburden and Sterility methods -Analytical method transfers: <u>IV Formulation Product:</u> <ul style="list-style-type: none">• Validate and transfer Assay and Related Substances (SG2, 4TFMBA, ST-246 Exo Isomer, Impurity A, SG1 hydrazide) by HPLC.• Trial alternative detection methods/techniques for SG1 Diacid• Validate and transfer Hydrazine• Verify Appearance of solution, pH, Particulate matter, Osmolality <u>Lyophilized Product (for development batch on stability):</u> Initial stability data for Assay/Related Substances and Hydrazine will be generated using analytical methods that will not be fully validated. -Assumes Appearance and ID on API. -Set up Analytical standards for Product to support release and stability testing (IV formulation).	
Validation Services	
-Validation CTM Line Assessment and Assessment Summary	\$8,000
Contract Lab testing to release Kleptose at DSM. Assumes 4 batches of Kleptose. Fee of \$8,400 per Kleptose batch.	\$33,600
Required set up activities for Kleptose. Full commercial set up is required since DSM will contract the testing. <ul style="list-style-type: none">• Create an RMIR for material• Create an analytical standard for testing material• Create a sampling protocol• Create LIMS template	\$12,400
Total:	\$202,900
ID test for final packaged CTM samples. (Optional)	\$2,400 per sample (Optional)

Batches:

Media Fills - not required due to change to DSM qualified 30cc liquid vial/stopper combination on the CTM line.	\$0
Lyo and Liquid Development Batch Manufacture (1) 50L batch split between Lyo and Liquid to support stability. Note: will not fill all of bulk into vials. - Assumes compounding in the CTM suite. Hand fill and lyophilize approximately 378 vials in the non-GMP area of Bldg 8 utilizing the 8 sq. ft. freeze dryer. - Assumes approximately a 50-60 hour lyo cycle. - For the Lyo portion - assumes a 50cc vial # 400015, 20mm stopper #005677 and Overseal # 013329. - Assumes ~600 vials to support the liquid formulation study. For the Liquid portion – assumes a 30cc vial	\$50,600
Liquid Placebo Batch (1) batch for Human Use (~1,800 vials). Must be completed in CTM Suite since a Human Use batch. Price includes set up of an analytical standard to support testing and stability.	See 1.3.1 of this proposal for batch pricing \$80,000
Liquid Active Batch (1) batch for Human Use (~1,800 vials) Must be completed in CTM Suite since for Human Use batch.	See 1.3.1 of this proposal for batch pricing \$80,000
Total:	\$210,600

Capital Estimate: \$26,840 See attachment #1 for additional information.

Stability Estimate: \$335,600

Study	Price
50cc Vial – One Lyo Development batch on stability	\$116,800
30cc Vial – One Liquid Development batch on stability	\$57,600
30cc Vial - One Liquid Active CTM batch on stability	\$89,500
30cc Vial - One Liquid Placebo CTM batch on stability	\$45,200
Photostability study	\$26,500

1. Testing based on ICH guidelines.
2. See Attachment #2 for stability protocols and time point pricing.

Section 2: Project Strategy

2.1 Project Scope

This project is intended to execute the clinical manufacturing transfer of ST-246 for SIGA to the CTM line in Steriles North. DSM will supply CTM product to SIGA. The strategy for executing this project is as follows:

SIGA's ST-246 is an aseptically filled liquid product in final dosage form. The product is intended for distribution in US clinical trials. The project requires at minimum the scope of work outlined in this proposal to qualify DSM as a site of manufacture for ST-246 CTM material.

The project's scope involves manufacturing, filling, and release of ST-246 CTM product and is therefore developmental in nature. As such, issues and unexpected outcomes are anticipated for which ongoing technical support by DSM may be required. Any unanticipated technical support is out of scope for this proposal.

In all aspects of this project, DSM is responsible for adhering to appropriate GMPs and sound defensible development or transfer plans which will be acceptable, in DSM's opinion, to current regulatory expectations.

2.2 CTM Strategy

2.2.1 Scope/ Contract Finalization

Following proposal approval, a CTM agreement that also contains quality terms will be approved by both organizations. After the CTM agreement is in place, the project will be initiated. Payment terms will be 14 days from invoice date.

2.2.2 Initial Process Feasibility/Transfer Activities

The CTM area Technical Representative will review the technical documents submitted by SIGA for the manufacture, filling and testing of ST-246. Documents to be prepared by DSM, with SIGA input and review should include formula and manufacturing instructions/batch record. SIGA will provide documents for API/BDS and product storage requirements.

Analytical services include:

- Set up Analytical standard for the API, Kleptose, IV Formulation and Lyo development Products
- Set up Analytical standard for the IV Formulation placebo batch
- Develop and Validate BET, Bioburden and Sterility Methods
- Assumes Appearance and ID on API.

Contract Lab testing to release Kleptose at DSM. Assumes 1 batch of Kleptose and fee applies to each batch if multiple batches are required.

Analytical method validation and transfers:

IV Formulation Product:

- Validate and transfer Assay and Related Substances (SG2, 4TFMBA, ST-246 Exo Isomer, Impurity A, SG1 hydrazide) by HPLC.
- Trial alternative detection methods/techniques for SG1 Diacid
- Validate and transfer Hydrazine
- Verify Appearance of solution, pH, Particulate matter and Osmolality.

The following testing and QA release is included in batch pricing: Appearance, Appearance of solution, pH, Assay/Related Substances by HPLC, Hydrazine, Total Impurities, Particulate Matter, Osmolality, PFB, Sterility, and BET.

Assumes DSM will ship samples to contract lab, Ricerca, for contract testing of SG1 Diacid.

2.2.3 CTM Services

CTM Batch – Multiple CTM batches are included in this proposal. All in process and finished product testing will be required.

One 30cc vial size - Liquid Development batch for stability only.
One 50cc vial size - Lyo Development batch for stability only.
One 30cc vial size - Liquid Placebo CTM batch
One 30cc vial size - Liquid Active CTM batch

2.2.4 Validation Services

Validation Services include a CTM Line Assessment and Assessment Summary.

Procedures for cleaning will be TOC for any equipment that is not disposable utilizing the DSM cleaning model. All filler product contact equipment is disposable.

2.2.5 Regulatory Services

DSM regulatory support activities are considered optional and are out of the scope of this proposal.

2.2.6 DSM Quality Assurance

DSM's Quality Assurance department will act as a compliance consultant and provide Quality oversight for adherence to regulatory requirements. This will include but not limited to the following: Documentation, Validation, and Investigations.

SIGA understands that DSM has considerable regulatory and compliance responsibility associated with this project. In all aspects of this project, DSM is responsible for adhering to appropriate GMPs and sound defensible development plans which will be acceptable, in DSM's opinion, to current regulatory expectations. DSM will not knowingly execute (or bypass) activities which are inconsistent with

the above or which will jeopardize DSM's regulatory status. At a minimum DSM's applicable Quality Systems must be met.

2.3 Standard Project Assumptions

2.3.1 General Assumptions

1. Project requires completion of a MSDS and assessment of Safety issues, potential environmental concerns, and waste disposal procedures, as appropriate, for this project. This proposal assumes the Chemical Health Protection rating is a CAT3 or less.
2. The API and excipients will be provided by the customer unless they are DSM current standard materials.
3. Customer will provide sufficient quantities of material for qualification of the BET and Sterility testing to be performed at DSM.
4. All materials supplied by SIGA Technologies, Inc. will arrive at DSM with appropriate documentation to be received into DSM's inventory, a certificate of analysis, certificate of compliance and chain of custody.
5. Standard DSM Documentation will be used for the filling process using the customer's critical parameters and process.
6. Storage condition of API and finished product will be controlled room temperature with ambient humidity.
7. A double sterile filtration will be performed.
8. Fill weight checks are part of the standard DSM process.
9. Inspection of the vials will include inspection for container closure and foreign matter (no product or cosmetic inspection). No retain samples will be taken or held at DSM.
10. Batch records review will be performed by DSM before QA release of the CTM batch. However upon request, product may be shipped under conditional status.
11. All unused material supplied by the customer will be returned or destroyed within 90 days of production if no additional demand is required.
12. Shipping of product, product samples, and documentation will be freight collect FOB Greenville. DSM will tender the materials to an approved carrier.

2.3.2 Optional Services Upon Request

- Regulatory Affairs documentation support.

2.3.3 Excluded materials or activities

Controlled or Cytotoxic substances are excluded materials from this production area.

1. DSM does not provide CTM labeling or final packaging at this time.
2. Phase III services are available and manufactured on commercial equipment.
3. Temperature controlled processing is not available on this equipment. Temperature controlled storage of API and finished product is available for specific temperature ranges.

2.4 Contacts Listing

Primary DSM contacts for this proposal are as follows:

Table 1: Contacts

Name	Phone number	Role	E-mail address
Diane Lever	510-524-2852	Sr. Account Director/Business Development	Diane.Lever@DSM.com
Ray Braxton	252-707-7240	CTM Manager-Technical Lead	Ray.braxton@DSM.com
Jennifer Adams	252-707-2049	Business Services	Jennifer.Adams@DSM.com

Attachment 1: Capital Estimate

Siga Technologies, Inc. (ST-246) Capital Estimate for CTM Line - North	
DESCRIPTION	BUDGET
50 ml vial size 20mm stopper, 25 ml fill - Lyo product	AMOUNT
EQUIPMENT	
Washer change parts (50 ml vial)	8,000
Misc. Tubing & Fittings and instruments	5,000
Filler change parts (50 ml vial)	8,000
FREIGHT	700
TAXES	700
ENGINEERING	2,000
Subtotal	24,400
CONTINGENCY @ 10%	2,440
Total	\$26,840
Change parts have ~6 to 8 week leadtime.	

Attachment 2: – Stability Protocols – (see next 5 pages)

Siga Technologies

ST-246 214 mg/vial

Package Presentation: 30 mL vial

One Storage Orientation

One CTM batch (liquid product) will be placed on stability (one stability study)

Study Attributes	Protocol Code
Physical Exam (Product Appearance of Liquid)	A
Active Potency (Complex HPLC Assay)	
Related Substances/Impurities (Same Complex HPLC Assay, no addn'l stds)	
Hydrazine (Complex HPLC Assay)	
pH	
SG1 Diacid	C
Particulate Matter (HIAC)	
Sterility	D
Bacterial Endotoxin (Gel Clot LAL)	

Study Activities and Use Fees

Thermal Chamber Use Fee (for 1 basket of samples per storage condition)	X
Sample labeling (for Sterile products)	
Stability framework, protocol, and database creation	Y
SLIM Database Reports	

Storage Conditions and Activities	Intervals in Months									
	0	1	3	6	9	12	18	24	36	48
Administrative	XY	Y	Y	Y	Y	Y	Y	Y	Y	Y
40C/75%RH	A,C,D ⁽¹⁾	A	A	A,C,D						
25C/60%RH		A	A	A,C	A	A,C,D	A	A,C	A	A
5C		A	A	A,C	A	A,C,D	A	A,C	A	A

⁽¹⁾ Assumed that Product Release Data will be used for the initial (T0) timepoint.

Price per Time point:	\$ 9,700	\$ 9,700	\$ 9,700	\$ 11,600	\$ 7,000	\$ 10,600	\$ 8,300	\$ 8,900	\$ 7,000	\$ 7,000	\$ 89,500
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Assumptions:

1) Analytical activities include the cost of reasonable and customary expendables associated with performing test methods, such as USP reference standards, solvents, and common HPLC columns, etc. However, some analyses may utilize especially numerous, particularly costly, or short-lived expendables, including limitedly available or expensive reference standards/markers as well as specialized, fragile, or short-lived HPLC columns, and other such "uncustomary" items. These limitedly available or atypically costly analytical items are not included in the analytical costs for this project and will either be provided by the client or billed to the client incrementally to the proposal price.

2) Assumed DSM has all required equipment and expertise to perform required tests (as listed in the bid).

3) Assumed that Product Release Data would be used for the initial (T0) timepoint.

4) The sample allocations provided by Siga are not sufficient to support these studies.

Siga Technologies
ST-246 214 mg/vial
Package Presentation: 30 mL vial - Liquid formulation
One Storage Orientation
One Placebo CTM batch placed on stability (one stability study)

Study Attributes	Protocol Code
Physical Exam (Product Appearance)	A
Active Potency (Complex HPLC Assay - Absence of Active)	A
Particulate Matter (HIAC)	C
Sterility	D
Bacterial Endotoxin (Gel Clot LAL)	D

Study Activities and Use Fees	
Thermal Chamber Use Fee (for 1 basket of samples per storage condition)	X
Sample labeling (for Sterile products)	X
Stability framework, protocol, and database creation	X
SLIM Database Reports	Y

Storage Conditions and Activities	Intervals in Months								
	0	1	3	6	9	12	18	24	36
Administrative	XY	Y	Y	Y	Y	Y	Y	Y	Y
40C/75%RH	A,B,C,D,I ⁽¹⁾	A	A	A,C,D					
25C/60%RH		A	A	A,C	A	A,C,D	A	A	A
5C		A	A	A,C	A	A,C,D	A	A	A

⁽¹⁾ Assumed that Product Release Data will be used for the initial (T0)

Price per Time point:
\$ 8,900
\$ 3,700
\$ 3,700
\$ 5,600
\$ 3,500
\$ 5,800
\$ 3,500
\$ 3,500
\$ 3,

- Assumptions:
- 1) Analytical activities include the cost of reasonable and customary expendables associated with performing test methods, such as USP reference standards, solvents, and common HPLC columns, etc. However, some analyses may utilize especially numerous, particularly costly, or short-lived expendables, including limitedly available or expensive reference standards/markers as well as specialized, fragile, or short-lived HPLC columns, and other such "uncustomary" items. These limitedly available or atypically costly analytical items are not included in the analytical costs for this project and will either be provided by the client or billed to the client incrementally to the proposal price.
2) Assumed DSM has all required equipment and expertise to perform required tests (as listed in the bid).
3) Assumed that Product Release Data would be used for the initial (T0) timepoint.
4) The sample allocations provided by Siga are not sufficient to support these studies.

Siga Technologies
ST-246 214 mg/vial
Package Presentation: 30 mL vial
One Storage Orientation
One Development batch (liquid product) will be placed on stability (one stability study)

Study Attributes	Protocol Code
Physical Exam (Product Appearance of Liquid)	A
Active Potency (Complex HPLC Assay)	
Related Substances/Impurities (Same Complex HPLC Assay, no addn'l stds)	
Hydrazine (Complex HPLC Assay)	
pH	
SG1 Diacid (Outsourced)	C
Particulate Matter (HIAC)	

Study Activities and Use Fees	
Thermal Chamber Use Fee (for 1 basket of samples per storage condition)	X
Sample labeling (for Sterile products)	
Stability framework, protocol, and database creation	Y
SLIM Database Reports	

Storage Conditions and Activities	Intervals in Months									
	0	1	3	6	9	12	18	24	36	48
Administrative	XY	Y	Y	Y	Y	Y	Y	Y	Y	Y
40C/75%RH	A,C ⁽¹⁾	A,C	A,C	A,C						
25C/60%RH		A	A	A	A	A,C	A	A,C	A	A
5C		A	A	A	A	A,C	A	A,C	A	A

⁽¹⁾ Assumed that Product Release Data will be used for the initial (T0) timepoint.

Price per Time point:	\$ 9,300	\$ 6,700	\$ 6,700	\$ 6,700	\$ 4,200	\$ 5,700	\$ 4,200	\$ 5,700	\$ 4,200	\$ 4,200	\$ 57,600
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- Assumptions:**
- 1) Analytical activities include the cost of reasonable and customary expendables associated with performing test methods, such as USP reference standards, solvents, and common HPLC columns, etc. However, some analyses may utilize especially numerous, particularly costly, or short-lived expendables, including limitedly available or expensive reference standards/markers as well as specialized, fragile, or short-lived HPLC columns, and other such "uncustomary" items. These limitedly available or atypically costly analytical items are not included in the analytical costs for this project and will either be provided by the client or billed to the client incrementally to the proposal price.
 - 2) Assumed DSM has all required equipment and expertise to perform required tests (as listed in the bid).
 - 3) Assumed that Product Release Data would be used for the initial (T0) timepoint.
 - 4) The sample allocations provided by Siga are not sufficient to support these studies.

Siga Technologies
ST-246 214 mg/vial
Package Presentation: 50 mL vial (Lyo product)
One Storage Orientation
One Development batch placed on stability (one stability study)

Study Attributes	Protocol Code
Physical Exam (Lyo Product Appearance)	A
Physical Exam (Reconstituted Product Appearance)	
Active Potency (Complex HPLC Assay)	
Related Substances/Impurities (Same Complex HPLC Assay, no addn'l stds)	
Hydrazine (Complex HPLC Assay)	
pH after reconstitution	
Dissolution/Reconstitution Time	
SG1 Diacid (Outsourced)	
Moisture Content (KF)	
Particulate Matter (HIAC)	C

Study Activities and Use Fees	
Thermal Chamber Use Fee (for 1 basket of samples per storage condition)	X
Sample labeling (for Sterile products)	
Stability framework, protocol, and database creation	Y
SLIM Database Reports	

Storage Conditions and Activities	Intervals in Months									
	0	1	3	6	9	12	18	24	36	48
Administrative	XY	Y	Y	Y	Y	Y	Y	Y	Y	Y
40C/75%RH	A,C ⁽¹⁾	A	A	A,C						
25C/60%RH			A	A	A	A,C	A	A,C	A	A
5C ⁽²⁾			A	A	A	A,C	A	A,C	A	A
timepoint.										

Price per Time point:	\$ 9,700	\$ 9,600	\$ 13,000	\$ 14,100	\$ 11,300	\$ 12,400	\$ 11,300	\$ 12,800	\$ 11,300	\$ 11,300	\$ 116,800
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Assumptions:

- Analytical activities include the cost of reasonable and customary expendables associated with performing test methods, such as USP reference standards, solvents, and common HPLC columns, etc. However, some analyses may utilize especially numerous, particularly costly, or short-lived expendables, including limitedly available or expensive reference standards/markers as well as specialized, fragile, or short-lived HPLC columns, and other such "uncustomary" items. These limitedly available or atypically costly analytical items are not included in the analytical costs for this project and will either be provided by the client or billed to the client incrementally to the proposal price.
- Assumed DSM has all required equipment and expertise to perform required tests (as listed in the bid).
- Assumed that Product Release Data would be used for the initial (T0) timepoint.
- The sample allocations provided by Siga are not sufficient to support these studies.

Siga

ST-246 (10 mg/mL)

Photostability per ICH Option 2 on the IV Formulation (one stability study)

Study Attributes	Protocol Code
Physical Exam (Product Appearance of Liquid)	A
Active Potency (Complex HPLC Assay)	
Related Substances/Impurities (Same Complex HPLC Assay, no addn'l stds)	
Hydrazine (Complex HPLC Assay)	
pH	
SG1 Diacid (Outsourced)	
Particulate Matter (HIAC)	

Study Activities and Use Fees	
Thermal Chamber Use Fee (for 1 basket of samples per storage condition)	X
Sample labeling (for Sterile products)	
Stability framework, protocol, and database creation	
Light Chamber Use Fee	
SLIM Database Reports	Y

Storage Conditions and Activities	Intervals in Months		Total
	0	0.5	
Administrative	XY	Y	
ICH Option 2 Photostability Chamber (Unpackaged in Open Dish)		A ⁽¹⁾	
ICH Option 2 Photostability Chamber (Unpackaged in Open Dish - Dark Control)		A ⁽¹⁾	
ICH Option 2 Photostability Chamber (in Primary Packaging)		A ⁽¹⁾	
ICH Option 2 Photostability Chamber (in Primary Package - Dark Control)		A ⁽¹⁾	
⁽¹⁾ Treatment will likely not coincide with other testing for other storage stations			
⁽²⁾ Tested only if Open Dish UV/Fluorescent Chamber condition fails			

Price per Time point:

\$	7,200	\$	19,300	\$	26,500
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- Assumptions:**
- Photostability will be performed per ICH Option 2.
 - The open dish exposure and primary packaging samples will be exposed and tested simultaneously.
 - Assumed photostability would not coincide with any other testing.
 - Assumed that we would only perform photostability on the IV formulation (demo batch).
 - Assumed that we have enough samples to perform the photostability of the IV demo batch.

**Amendment 2 to Exhibit C to the
Services Agreement
Dated 12 January 2012**

Statement of Work #3

This Amendment 2 hereby modifies and is made an integral part of Statement of Work #3 ("SOW #3") between SIGA Technologies, Inc. ("SIGA") and DSM Pharmaceuticals, Inc. ("Company"), which was entered into pursuant to the Master Services Agreement between SIGA and Company dated January 12, 2012 ("SA").

Under and subject to the terms and conditions of the SA, SIGA and Company wish to amend and revise the scope of the services set forth in SOW #3 as set forth below.

SIGA and Company agree as follows:

1. Revised Scope of Services

The Scope of Services is applicable to **CTM Transfer Services** including **Analytical Services, Validation Services, Kleptose Release Testing and Kleptose Set-up Activities** and is revised as presented in **Scope Change – Tecovirimat (ST-246 ®) Injection, Analytical Standard Revision** dated **21 September 2012** attached hereto as Schedule A.

2. Fees and Payment Terms

Total charges for professional service fees and direct expenses for this Scope Change will not exceed \$5,700 bringing the total ceiling of Exhibit C to a not to exceed amount of **\$208,600**. Upon the full execution of this Amendment 2, and unless the parties otherwise agree, Company shall invoice SIGA on a monthly basis for work performed as it relates to the Revised Scope of Services. SIGA agrees to pay to Company according to the terms set forth in Paragraph 4 of the above-referenced SA.

Term

Services will commence upon full execution of this Amendment 2 and will be completed by December 31, 2012.

This Amendment 2 is issued pursuant to and, upon its full execution by SIGA and Company, shall become incorporated into SOW #3, which is incorporated into the SA.

The foregoing is the complete and final expression of the agreement between SIGA and Company to modify SOW #3 with respect to the Revised Scope of Services and cannot be modified, except by a writing signed by duly authorized representatives of both SIGA and Company.

By signing below, the authorized parties agree to the terms of this Amendment 2, effective as of the date of last signature below.

SIGA Technologies, Inc.

BY: Dennis E. Hruby DATE: 06 Nov 2012
NAME: Dennis E. Hruby, Ph.D.
TITLE: Chief Scientific Officer

DSM Pharmaceuticals, Inc.

BY: Lawrence P Thomas DATE: 08 Nov 2012
NAME: Lawrence P Thomas
TITLE: V.P. Marketing & Sales

SCHEDULE A



DSM Pharmaceuticals, Inc.
5900 Martin Luther King Jr. Highway
Greenville, North Carolina 27834

September 21, 2012

Stephen Priebe, Ph.D.
4575 SW Research Way
Corvallis OR 97333

Re: Scope Change - Tecovirimat (ST-246 ®) Injection, Analytical Standard Revision

Dear Stephen:

Please find below the pricing for Tecovirimat (ST-246 ®) Injection analytical standard revision. The price includes revision of three current analytical standards to include the reporting instruction for the Total Related Substances.

Support Services

	Price
Revise three current analytical standards to include the reporting instruction for the Total Related Substances	\$5,700

The services under this Scope Change shall be conducted under and subject to the terms and conditions of the Services Agreement between SIGA and DSM dated January 12, 2012.

Please provide approval by signing below and send an executed copy and purchase order to my attention, via e-mail in PDF format.

Please feel free to contact me at 858.945.5332 should you have any questions.

SIGA Approval: *Dennis E. Huley* Date: 06 Nov 2012
PO Number: 16173-031312

Kind Regards,

Diane V. Lever

Diane V. Lever
Sr. Account Director/Business Development

cc: Jennifer Adams
Shumena Horton
Kaye Byrd
Judy Moore

**Exhibit E to the
Services Agreement
Dated 12 January 2012**

Statement of Work #5

This Exhibit details the services that Company will provide to SIGA. The services under this Exhibit shall be conducted under and subject to the terms and conditions of the Services Agreement between SIGA and Company, hereinafter ("SA").

Scope of Services

The Scope of Services is applicable to the manufacture of one (1) liquid placebo batch of ST-246 CTM for human use (~1,800 vials), one (1) liquid active batch of ST-246 CTM for human use (~1,800 vials), and corresponding stability through the 1 month interval as presented in ST-246 Clinical Batch Proposal, Version 8, dated 20 July 2012 (see attachment A). The remaining stability intervals will be covered under a separate Exhibit and Purchase Order.

Payment Terms

Total charges for professional service fees and direct expenses will not exceed **\$192,000**. Upon the execution of this Exhibit, and unless the parties otherwise agree, Company shall invoice SIGA in the following manner:

Manufacture of one (1) liquid placebo batch (\$80,000) – on a monthly basis at the time of initiation;

Manufacture of one (1) liquid active batch (\$80,000) – on a monthly basis at the time of initiation;

Stability through 1 month: Placebo (\$8,900, \$3,700) – at each interval after the stability report is issued.

Stability through 1 month: Active (\$9,700, \$9,700) – at each interval after the stability report is issued.

SIGA agrees to pay to Company according to the terms set forth in Paragraph 4 of the above-referenced SA.

Term of this Exhibit

Services will commence upon execution of this Exhibit and will be completed by December 31, 2012.

SIGA Technologies, Inc.

By: Dennis E. Hraby
Name: Dennis E. Hraby, Ph.D.
Title: Chief Scientific Officer
Date: 30 Jul 2012

DSM Pharmaceuticals

By: Jana L. Tarkenton
Name: Jana L. Tarkenton
Title: President & Business Unit Director
Date: 6 Sep 2012

Attachment A



ST-246 Clinical Batch Proposal

**Issued July 20, 2012
Version 8
for
SIGA Technologies, Inc.**

**Submitted By:
Diane Lever, Sr. Account Director/Business Development**

DSM Pharmaceuticals, Inc.
5900 Martin Luther King Jr. Highway
Greenville, NC 27834
www.dsmpharmaceuticalproducts.com

SIGA-ST-246

CONTENTS

Section 1: Executive Summary

- 1.1 Introduction
- 1.2 Proposal Summary
- 1.3 Terms of Supply

Section 2: Project Strategy

- 2.1 Standard Project Assumptions
- 2.2 Contacts Listing

Attachments

- Attachment 1: Capital
- Attachment 2: Stability

Section 1: Executive Summary

1.1 Introduction

DSM Pharmaceuticals Inc. (DPI) is a leading provider of product Development, Manufacturing and Packaging services to global Pharmaceutical & Biotechnology companies. Through continuous Investment and Innovation, and with a commitment to Quality and Security of Supply, DPI strives to be the preferred partner of choice for the production of sterile & solid dosage forms. Delivering outstanding service & value to our customers, combined with our experience, relevant expertise and state-of-the-art equipment, makes us uniquely qualified to support product success.

DPI Delivers **Total Value** to its Customers:

- A **Sustainable** Business Partner
 - 100 Year Legacy of Royal DSM N.V.
 - World Leader on the Dow Jones Sustainability Index
 - Solid, Independent Financial Position
- A **Compelling Facility**
 - 1.5MM square feet over 640 acres
 - All service offerings based at one site
 - DSM capital investment of \$176MM since 2001
- An **Unparalleled Level of Experience**
 - Continuous operations in Greenville, NC for 40 years
 - Development, Manufacturing & Packaging services
 - Average staff tenure of 14 years
 - Repeatedly launch 10 or more new products annually
- **Premium Quality** Systems & Processes
 - Fully-integrated, computerized systems such as SAP, Documentum and Trackwise
 - Proprietary, oracle-based software system called iMost, for planning, scheduling and as a data hub, offering complete visibility into production status
- Demonstrated **Regulatory Excellence**
 - Extraordinary international agency audit history
 - More than 90% of PAIs waived since 2007
- **DEA Licensed** Facility
 - Licensed to manufacture CII-CV products

DSM Pharmaceuticals, Inc. appreciates the opportunity to propose clinical trial material (CTM) pricing to **SIGA Technologies, Inc.** for **ST-246**, and looks forward to further discussions to ensure we fully address your team's specific needs. We are confident that DPI offers unique advantages, making us the best CMO option. DPI's leadership position in the CMO sector is driven by collaborative partnerships, with the goal of mutual success.

DSM Pharmaceuticals, Inc. wishes to thank SIGA Technologies, Inc. for their consideration of our experience, expertise and Commitment to Excellence.

1.2 Proposal Summary

This proposal is focused on providing pricing for early phase clinical liquid ST-246 product utilizing a 30cc qualified container closure system on DSM's CTM line for SIGA Technologies, Inc.

1.3 Terms of Supply

1.3.1 CTM Price

Batch Type	Batch Size Vials	Per Batch Price	Tiers
ST-246 (30mL vial) CTM	~1,800	\$80,000	1-2 CTM batches
ST-246 (30mL vial) CTM	~1,800	\$75,000	3-4 CTM batches
ST-246 (30mL vial) CTM	~1,800	\$70,000	> 4 CTM batches

- Price includes manufacturing, filling and bulk packaging into shippers.
- The following testing and QA release is included in price above:
Appearance, pH, Assay/Related Substances by HPLC, Hydrazine, Total Impurities, Particulate Matter, Osmolality, PFB, Sterility, and BET.
Assumes DSM will ship samples to Ricerca for contract testing of SG1Diacid.
- Price does not include the active ingredient or Kleptose, to be provided by SIGA Technologies, Inc.
- Assumes a 22mL fill volume.
- The container/closure to be used is a 30cc vial within DSM inventory. This vial and stopper is qualified on the CTM Line. DSM component item numbers: 30cc vial #321649, 20mm Stopper # 005305, Cap # 013329.
- Assumes product does not require nude vial labeling.
- Rescheduling fee of \$10,000 will be charged for changes within the 30-day firm zone. A CTM agreement that also contains quality terms will be required prior to manufacture of CTM batches.

CTM Transfer Services and Activities

Description	Pricing
Project Management Support Analytical Services -Develop and validate BET, Bioburden and Sterility methods -Analytical method transfers: <u>IV Formulation Product:</u> <ul style="list-style-type: none"> • Validate and transfer Assay and Related Substances (SG2, 4TFMBA, ST-246 Exo Isomer, Impurity A, SG1 hydrazide) by HPLC. • Trial alternative detection methods/techniques for SG1 Diacid • Validate and transfer Hydrazine • Verify Appearance of solution, pH, Particulate matter, Osmolality <u>Lyophilized Product (for development batch on stability):</u> Initial stability data for Assay/Related Substances and Hydrazine will be generated using analytical methods that will not be fully validated.	\$148,900
Validation Services -Validation CTM Line Assessment and Assessment Summary	\$8,000
Contract Lab testing to release Kleptose at DSM. Assumes 4 batches of Kleptose. Fee of \$8,400 per Kleptose batch.	\$33,600
Required set up activities for Kleptose. Full commercial set up is required since DSM will contract the testing. <ul style="list-style-type: none"> • Create an RMIR for material • Create an analytical standard for testing material • Create a sampling protocol • Create LIMS template 	\$12,400
Total:	\$202,900
ID test for final packaged CTM samples. (Optional)	\$2,400 per sample (Optional)

Batches:

Media Fills - not required due to change to DSM qualified 30cc liquid vial/stopper combination on the CTM line.	\$0
Lyo and Liquid Development Batch Manufacture (1) 50L batch split between Lyo and Liquid to support stability. Note: will not fill all of bulk into vials. - Assumes compounding in the CTM suite. Hand fill and lyophilize approximately 378 vials in the non-GMP area of Bldg 8 utilizing the 8 sq. ft. freeze dryer. - Assumes approximately a 50-60 hour lyo cycle. - For the Lyo portion - assumes a 50cc vial # 400015, 20mm stopper #005677 and Overseal # 013329. - Assumes ~600 vials to support the liquid formulation study. For the Liquid portion – assumes a 30cc vial	\$50,600
Liquid Placebo Batch (1) batch for Human Use (~1,800 vials). Must be completed in CTM Suite since a Human Use batch. Price includes set up of an analytical standard to support testing and stability.	See 1.3.1 of this proposal for batch pricing \$80,000
Liquid Active Batch (1) batch for Human Use (~1,800 vials) Must be completed in CTM Suite since for Human Use batch.	See 1.3.1 of this proposal for batch pricing \$80,000
Total:	\$210,600

Capital Estimate: \$26,840 See attachment #1 for additional information.

Stability Estimate: \$335,600

Study	Price
50cc Vial – One Lyo Development batch on stability	\$116,800
30cc Vial – One Liquid Development batch on stability	\$57,600
30cc Vial - One Liquid Active CTM batch on stability	\$89,500
30cc Vial - One Liquid Placebo CTM batch on stability	\$45,200
Photostability study	\$26,500

1. Testing based on ICH guidelines.
2. See Attachment #2 for stability protocols and time point pricing.

Section 2: Project Strategy

2.1 Project Scope

This project is intended to execute the clinical manufacturing transfer of ST-246 for SIGA to the CTM line in Steriles North. DSM will supply CTM product to SIGA. The strategy for executing this project is as follows:

SIGA's ST-246 is an aseptically filled liquid product in final dosage form. The product is intended for distribution in US clinical trials. The project requires at minimum the scope of work outlined in this proposal to qualify DSM as a site of manufacture for ST-246 CTM material.

The project's scope involves manufacturing, filling, and release of ST-246 CTM product and is therefore developmental in nature. As such, issues and unexpected outcomes are anticipated for which ongoing technical support by DSM may be required. Any unanticipated technical support is out of scope for this proposal.

In all aspects of this project, DSM is responsible for adhering to appropriate GMPs and sound defensible development or transfer plans which will be acceptable, in DSM's opinion, to current regulatory expectations.

2.2 CTM Strategy

2.2.1 Scope/ Contract Finalization

Following proposal approval, a CTM agreement that also contains quality terms will be approved by both organizations. After the CTM agreement is in place, the project will be initiated. Payment terms will be 14 days from invoice date.

2.2.2 Initial Process Feasibility/Transfer Activities

The CTM area Technical Representative will review the technical documents submitted by SIGA for the manufacture, filling and testing of ST-246. Documents to be prepared by DSM, with SIGA input and review should include formula and manufacturing instructions/batch record. SIGA will provide documents for API/BDS and product storage requirements.

Analytical services include:

- Set up Analytical standard for the API, Kleptose, IV Formulation and Lyo development Products
- Set up Analytical standard for the IV Formulation placebo batch
- Develop and Validate BET, Bioburden and Sterility Methods
- Assumes Appearance and ID on API.

Contract Lab testing to release Kleptose at DSM. Assumes 1 batch of Kleptose and fee applies to each batch if multiple batches are required.

Analytical method validation and transfers:

IV Formulation Product:

- Validate and transfer Assay and Related Substances (SG2, 4TFMBA, ST-246 Exo Isomer, Impurity A, SG1 hydrazide) by HPLC.
- Trial alternative detection methods/techniques for SG1 Diacid
- Validate and transfer Hydrazine
- Verify Appearance of solution, pH, Particulate matter and Osmolality.

The following testing and QA release is included in batch pricing: Appearance, Appearance of solution, pH, Assay/Related Substances by HPLC, Hydrazine, Total Impurities, Particulate Matter, Osmolality, PFB, Sterility, and BET.

Assumes DSM will ship samples to contract lab, Ricerca, for contract testing of SG1 Diacid.

2.2.3 CTM Services

CTM Batch – Multiple CTM batches are included in this proposal. All in process and finished product testing will be required.

One 30cc vial size - Liquid Development batch for stability only.
One 50cc vial size - Lyo Development batch for stability only.
One 30cc vial size - Liquid Placebo CTM batch
One 30cc vial size - Liquid Active CTM batch

2.2.4 Validation Services

Validation Services include a CTM Line Assessment and Assessment Summary.

Procedures for cleaning will be TOC for any equipment that is not disposable utilizing the DSM cleaning model. All filler product contact equipment is disposable.

2.2.5 Regulatory Services

DSM regulatory support activities are considered optional and are out of the scope of this proposal.

2.2.6 DSM Quality Assurance

DSM's Quality Assurance department will act as a compliance consultant and provide Quality oversight for adherence to regulatory requirements. This will include but not limited to the following: Documentation, Validation, and Investigations.

SIGA understands that DSM has considerable regulatory and compliance responsibility associated with this project. In all aspects of this project, DSM is responsible for adhering to appropriate GMPs and sound defensible development plans which will be acceptable, in DSM's opinion, to current regulatory expectations. DSM will not knowingly execute (or bypass) activities which are inconsistent with

the above or which will jeopardize DSM's regulatory status. At a minimum DSM's applicable Quality Systems must be met.

2.3 Standard Project Assumptions

2.3.1 General Assumptions

1. Project requires completion of a MSDS and assessment of Safety issues, potential environmental concerns, and waste disposal procedures, as appropriate, for this project. This proposal assumes the Chemical Health Protection rating is a CAT3 or less.
2. The API and excipients will be provided by the customer unless they are DSM current standard materials.
3. Customer will provide sufficient quantities of material for qualification of the BET and Sterility testing to be performed at DSM.
4. All materials supplied by SIGA Technologies, Inc. will arrive at DSM with appropriate documentation to be received into DSM's inventory, a certificate of analysis, certificate of compliance and chain of custody.
5. Standard DSM Documentation will be used for the filling process using the customer's critical parameters and process.
6. Storage condition of API and finished product will be controlled room temperature with ambient humidity.
7. A double sterile filtration will be performed.
8. Fill weight checks are part of the standard DSM process.
9. Inspection of the vials will include inspection for container closure and foreign matter (no product or cosmetic inspection). No retain samples will be taken or held at DSM.
10. Batch records review will be performed by DSM before QA release of the CTM batch. However upon request, product may be shipped under conditional status.
11. All unused material supplied by the customer will be returned or destroyed within 90 days of production if no additional demand is required.
12. Shipping of product, product samples, and documentation will be freight collect FOB Greenville. DSM will tender the materials to an approved carrier.

2.3.2 Optional Services Upon Request

- Regulatory Affairs documentation support.

2.3.3 Excluded materials or activities

Controlled or Cytotoxic substances are excluded materials from this production area.

1. DSM does not provide CTM labeling or final packaging at this time.
2. Phase III services are available and manufactured on commercial equipment.
3. Temperature controlled processing is not available on this equipment. Temperature controlled storage of API and finished product is available for specific temperature ranges.

2.4 Contacts Listing

Primary DSM contacts for this proposal are as follows:

Table 1: Contacts

Name	Phone number	Role	E-mail address
Diane Lever	510-524-2852	Sr. Account Director/Business Development	Diane.Lever@DSM.com
Ray Braxton	252-707-7240	CTM Manager-Technical Lead	Ray.braxton@DSM.com
Jennifer Adams	252-707-2049	Business Services	Jennifer.Adams@DSM.com

Attachment 1: Capital Estimate

Siga Technologies, Inc. (ST-246) Capital Estimate for CTM Line - North	
DESCRIPTION	BUDGET
50 ml vial size 20mm stopper, 25 ml fill - Lyo product	AMOUNT
EQUIPMENT	
Washer change parts (50 ml vial)	8,000
Misc. Tubing & Fittings and instruments	5,000
Filler change parts (50 ml vial)	8,000
FREIGHT	700
TAXES	700
ENGINEERING	2,000
Subtotal	24,400
CONTINGENCY @ 10%	2,440
Total	\$26,840
Change parts have ~6 to 8 week leadtime.	

Attachment 2: – Stability Protocols – (see next 5 pages)

Siga Technologies**ST-246 214 mg/vial****Package Presentation: 30 mL vial****One Storage Orientation****One CTM batch (liquid product) will be placed on stability (one stability study)**

Study Attributes	Protocol Code
Physical Exam (Product Appearance of Liquid)	A
Active Potency (Complex HPLC Assay)	
Related Substances/Impurities (Same Complex HPLC Assay, no addn'l stds)	
Hydrazine (Complex HPLC Assay)	
pH	
SG1 Diacid	C
Particulate Matter (HIAC)	
Sterility	D
Bacterial Endotoxin (Gel Clot LAL)	

Study Activities and Use Fees

Thermal Chamber Use Fee (for 1 basket of samples per storage condition)	X
Sample labeling (for Sterile products)	
Stability framework, protocol, and database creation	Y
SLIM Database Reports	

Storage Conditions and Activities	Intervals in Months									
	0	1	3	6	9	12	18	24	36	48
Administrative	XY	Y	Y	Y	Y	Y	Y	Y	Y	Y
40C/75%RH	A,C,D ⁽¹⁾	A	A	A,C,D						
25C/60%RH		A	A	A,C	A	A,C,D	A	A,C	A	A
5C		A	A	A,C	A	A,C,D	A	A,C	A	A

⁽¹⁾ Assumed that Product Release Data will be used for the initial (T0) timepoint.

Price per Time point:	\$ 9,700	\$ 9,700	\$ 9,700	\$ 11,600	\$ 7,000	\$ 10,600	\$ 8,300	\$ 8,900	\$ 7,000	\$ 7,000	\$ 89,500
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Assumptions:

1) Analytical activities include the cost of reasonable and customary expendables associated with performing test methods, such as USP reference standards, solvents, and common HPLC columns, etc. However, some analyses may utilize especially numerous, particularly costly, or short-lived expendables, including limitedly available or expensive reference standards/markers as well as specialized, fragile, or short-lived HPLC columns, and other such "uncustomary" items. These limitedly available or atypically costly analytical items are not included in the analytical costs for this project and will either be provided by the client or billed to the client incrementally to the proposal price.

2) Assumed DSM has all required equipment and expertise to perform required tests (as listed in the bid).

3) Assumed that Product Release Data would be used for the initial (T0) timepoint.

4) The sample allocations provided by Siga are not sufficient to support these studies.

Siga Technologies
ST-246 214 mg/vial
Package Presentation: 30 mL vial - Liquid formulation
One Storage Orientation
One Placebo CTM batch placed on stability (one stability study)

Study Attributes	Protocol Code
Physical Exam (Product Appearance)	A
Active Potency (Complex HPLC Assay - Absence of Active)	A
Particulate Matter (HIAC)	C
Sterility	D
Bacterial Endotoxin (Gel Clot LAL)	D

Study Activities and Use Fees

Thermal Chamber Use Fee (for 1 basket of samples per storage condition)	X
Sample labeling (for Sterile products)	X
Stability framework, protocol, and database creation	X
SLIM Database Reports	Y

Storage Conditions and Activities	Intervals in Months								
	0	1	3	6	9	12	18	24	36
Administrative	XY	Y	Y	Y	Y	Y	Y	Y	Y
40C/75%RH	A,B,C,D,I ⁽¹⁾	A	A	A,C,D					
25C/60%RH		A	A	A,C	A	A,C,D	A	A	A
5C		A	A	A,C	A	A,C,D	A	A	A

⁽¹⁾ Assumed that Product Release Data will be used for the initial (T0)

Price per Time point: \$ 8,900 \$ 3,700 \$ 3,700 \$ 5,600 \$ 3,500 \$ 5,800 \$ 3,500 \$ 3,500 \$ 3,500

Assumptions:

- 1) Analytical activities include the cost of reasonable and customary expendables associated with performing test methods, such as USP reference standards, solvents, and common HPLC columns, etc. However, some analyses may utilize especially numerous, particularly costly, or short-lived expendables, including limitedly available or expensive reference standards/markers as well as specialized, fragile, or short-lived HPLC columns, and other such "uncustomary" items. These limitedly available or atypically costly analytical items are not included in the analytical costs for this project and will either be provided by the client or billed to the client incrementally to the proposal price.
- 2) Assumed DSM has all required equipment and expertise to perform required tests (as listed in the bid).
- 3) Assumed that Product Release Data would be used for the initial (T0) timepoint.
- 4) The sample allocations provided by Siga are not sufficient to support these studies.

Siga Technologies**ST-246 214 mg/vial****Package Presentation: 30 mL vial****One Storage Orientation****One Development batch (liquid product) will be placed on stability (one stability study)**

Study Attributes	Protocol Code
Physical Exam (Product Appearance of Liquid)	A
Active Potency (Complex HPLC Assay)	
Related Substances/Impurities (Same Complex HPLC Assay, no addn'l stds)	
Hydrazine (Complex HPLC Assay)	
pH	
SG1 Diacid (Outsourced)	C
Particulate Matter (HIAC)	

Study Activities and Use Fees

Thermal Chamber Use Fee (for 1 basket of samples per storage condition)	X
Sample labeling (for Sterile products)	
Stability framework, protocol, and database creation	Y
SLIM Database Reports	

Storage Conditions and Activities	Intervals in Months									
	0	1	3	6	9	12	18	24	36	48
Administrative	XY	Y	Y	Y	Y	Y	Y	Y	Y	Y
40C/75%RH	A,C ⁽¹⁾	A,C	A,C	A,C						
25C/60%RH		A	A	A	A	A,C	A	A,C	A	A
5C		A	A	A	A	A,C	A	A,C	A	A

⁽¹⁾ Assumed that Product Release Data will be used for the initial (T0) timepoint.

Price per Time point:	\$ 9,300	\$ 6,700	\$ 6,700	\$ 6,700	\$ 4,200	\$ 5,700	\$ 4,200	\$ 5,700	\$ 4,200	\$ 4,200	\$ 57,600
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Assumptions:

1) Analytical activities include the cost of reasonable and customary expendables associated with performing test methods, such as USP reference standards, solvents, and common HPLC columns, etc. However, some analyses may utilize especially numerous, particularly costly, or short-lived expendables, including limitedly available or expensive reference standards/markers as well as specialized, fragile, or short-lived HPLC columns, and other such "uncustomary" items. These limitedly available or atypically costly analytical items are not included in the analytical costs for this project and will either be provided by the client or billed to the client incrementally to the proposal price.

2) Assumed DSM has all required equipment and expertise to perform required tests (as listed in the bid).

3) Assumed that Product Release Data would be used for the initial (T0) timepoint.

4) The sample allocations provided by Siga are not sufficient to support these studies.

Siga Technologies**ST-246 214 mg/vial****Package Presentation: 50 mL vial (Lyo product)****One Storage Orientation****One Development batch placed on stability (one stability study)****Study Attributes****Protocol Code**

Physical Exam (Lyo Product Appearance)	A
Physical Exam (Reconstituted Product Appearance)	
Active Potency (Complex HPLC Assay)	
Related Substances/Impurities (Same Complex HPLC Assay, no addn'l stds)	
Hydrazine (Complex HPLC Assay)	
pH after reconstitution	
Dissolution/Reconstitution Time	
SG1 Diacid (Outsourced)	
Moisture Content (KF)	
Particulate Matter (HIAC)	C

Study Activities and Use Fees

Thermal Chamber Use Fee (for 1 basket of samples per storage condition)	X
Sample labeling (for Sterile products)	
Stability framework, protocol, and database creation	Y
SLIM Database Reports	

Storage Conditions and Activities	Intervals in Months									
	0	1	3	6	9	12	18	24	36	48
Administrative	XY	Y	Y	Y	Y	Y	Y	Y	Y	Y
40C/75%RH	A,C ⁽¹⁾	A	A	A,C						
25C/60%RH			A	A	A	A,C	A	A,C	A	A
5C ⁽²⁾			A	A	A	A,C	A	A,C	A	A
timepoint.										

Price per Time point: \$ 9,700 \$ 9,600 \$ 13,000 \$ 14,100 \$ 11,300 \$ 12,400 \$ 11,300 \$ 12,800 \$ 11,300 \$ 11,300 \$ 116,800

Assumptions:

1) Analytical activities include the cost of reasonable and customary expendables associated with performing test methods, such as USP reference standards, solvents, and common HPLC columns, etc. However, some analyses may utilize especially numerous, particularly costly, or short-lived expendables, including limitedly available or expensive reference standards/markers as well as specialized, fragile, or short-lived HPLC columns, and other such "uncustomary" items. These limitedly available or atypically costly analytical items are not included in the analytical costs for this project and will either be provided by the client or billed to the client incrementally to the proposal price.

2) Assumed DSM has all required equipment and expertise to perform required tests (as listed in the bid).

3) Assumed that Product Release Data would be used for the initial (T0) timepoint.

4) The sample allocations provided by Siga are not sufficient to support these studies.

Siga

ST-246 (10 mg/mL)

Photostability per ICH Option 2 on the IV Formulation (one stability study)

Study Attributes	Protocol Code
Physical Exam (Product Appearance of Liquid)	A
Active Potency (Complex HPLC Assay)	
Related Substances/Impurities (Same Complex HPLC Assay, no addn'l stds)	
Hydrazine (Complex HPLC Assay)	
pH	
SG1 Diacid (Outsourced)	
Particulate Matter (HIAC)	

Study Activities and Use Fees

Thermal Chamber Use Fee (for 1 basket of samples per storage condition)	X
Sample labeling (for Sterile products)	
Stability framework, protocol, and database creation	
Light Chamber Use Fee	
SLIM Database Reports	Y

Storage Conditions and Activities	Intervals in Months		Total
	0	0.5	
Administrative	XY	Y	
ICH Option 2 Photostability Chamber (Unpackaged in Open Dish)		A ⁽¹⁾	
ICH Option 2 Photostability Chamber (Unpackaged in Open Dish - Dark Control)		A ⁽¹⁾	
ICH Option 2 Photostability Chamber (in Primary Packaging)		A ⁽¹⁾	
ICH Option 2 Photostability Chamber (in Primary Package - Dark Control)		A ⁽¹⁾	
⁽¹⁾ Treatment will likely not coincide with other testing for other storage stations			
⁽²⁾ Tested only if Open Dish UV/Fluorescent Chamber condition fails			

Price per Time point: \$ 7,200 \$ 19,300 \$ 26,500

Assumptions:

- 1) Photostability will be performed per ICH Option 2.
- 2) The open dish exposure and primary packaging samples will be exposed and tested simultaneously.
- 3) Assumed photostability would not coincide with any other testing.
- 4) Assumed that we would only perform photostability on the IV formulation (demo batch).
- 5) Assumed that we have enough samples to perform the photostability of the IV demo batch.

**Amendment 1 to Exhibit E to the
Services Agreement
Dated 12 January 2012**

Statement of Work #5

This Amendment 1 hereby modifies and is made an integral part of Statement of Work #5 ("SOW #5") between SIGA Technologies, Inc. ("SIGA") and DSM Pharmaceuticals, Inc. ("Company"), which was entered into pursuant to the Master Services Agreement between SIGA and Company dated January 12, 2012 ("SA").

Under and subject to the terms and conditions of the SA, SIGA and Company wish to amend and revise the scope of the services set forth in SOW #5 as set forth below.

SIGA and Company agree as follows:

Scope of Services

The Scope of Services covered under SOW 5 is applicable to the manufacture of one (1) liquid placebo batch of ST-246 CTM for human use (~1,800 vials), one (1) liquid active batch of ST-246 CTM for human use (~1,800 vials), and corresponding stability through the 1 month interval as originally presented in ST-246 Clinical Batch Proposal, Version 8, dated 20 July 2012 (see attachment B). **The revision in the scope of services is applicable to the stability studies (see attachment A) through the one month interval for the placebo and active batches of CTM for human use.** The remaining stability intervals will be covered under a separate Exhibit and Purchase Order.

Payment Terms

Total charges for professional service fees and direct expenses will not exceed **\$192,300**. Upon the execution of this Exhibit, and unless the parties otherwise agree, Company shall invoice SIGA in the following manner:

Manufacture of one (1) liquid placebo batch (\$80,000) – on a monthly basis at the time of initiation;

Manufacture of one (1) liquid active batch (\$80,000) – on a monthly basis at the time of initiation;

Stability through 1 month: Placebo (\$9,900, \$1,900) – at each interval after the stability report is issued.

Stability through 1 month: Active (\$10,800, \$9,700) – at each interval after the stability report is issued.

SIGA agrees to pay to Company according to the terms set forth in Paragraph 4 of the above-referenced SA.

Term of this Exhibit

Services will commence upon execution of this Exhibit and will be completed by December 31, 2012.

This Amendment 1 is issued pursuant to and, upon its full execution by SIGA and Company, shall become incorporated into SOW #5, which is incorporated into the SA.

The foregoing is the complete and final expression of the agreement between SIGA and Company to modify SOW #5 with respect to the Revised Scope of Services and cannot be modified, except by a writing signed by duly authorized representatives of both SIGA and Company.

By signing below, the authorized parties agree to the terms of this Amendment 1, effective as of the date of last signature below.

SIGA Technologies, Inc.

By: Dennis E. Hruby
Name: Dennis E. Hruby, Ph.D.
Title: Chief Scientific Officer

Date: 10 Sep 2012

DSM Pharmaceuticals

By: Lawrence P Thomas
Name: Lawrence P Thomas
Title: V.P. Marketing & Sales
Date: 2 Nov 2012

Attachment A

Siga Technologies

ST-246 214 mg/vial

Package Presentation: 30 mL vial - Liquid formulation

One Storage Orientation

One Placebo CTM batch placed on stability (one stability study)

Study Attributes	Protocol Code
Physical Exam (Product Appearance)	A
pH	A
Particulate Matter (HIAC)	B
Sterility	C
Bacterial Endotoxin (Gel Clot LAL)	D

Study Activities and Use Fees

Thermal Chamber Use Fee (for 1 basket of samples per storage condition)	X
Sample labeling (for Sterile products)	X
Stability framework, protocol, and database creation	X
SLIM Database Reports	Y

Storage Conditions and Activities	Intervals in Months											Total
	0	1	3	6	9	12	18	24	36	48	60	
Administrative	XY	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	
40C/75%RH	A,B,C,D,I ⁽¹⁾	A, B	A	A, B								
25C/60%RH		A, B	A	A, B	A	A,B,C	A	A,B,C	A	A	A	
5C		A, B	A	A, B	A	A,B,C	A	A,B,C	A, B	A, B	A, B	
timepoint.												
Price per Time point:	\$ 9,900	\$ 1,900	\$ 1,300	\$ 1,900	\$ 1,100	\$ 2,800	\$ 1,100	\$ 2,800	\$ 1,500	\$ 1,500	\$ 1,500	\$ 27,300

Assumptions:

- 1) Analytical activities include the cost of reasonable and customary expendables associated with performing test methods, such as USP reference standards, solvents, and common HPLC columns, etc. However, some analyses may utilize especially numerous, par
- 2) Assumed DSM has all required equipment and expertise to perform required tests (as listed in the bid).
- 3) Assumed that Product Release Data would be used for the initial (T0) timepoint.
- 4) The sample allocations provided by Siga are not sufficient to support these studies.

Siga Technologies**ST-246 214 mg/vial****Package Presentation: 30 mL vial****One Storage Orientation****One CTM batch (liquid product) will be placed on stability (one stability study)**

Study Attributes	Protocol Code
Physical Exam (Product Appearance of Liquid)	A
Active Potency (Complex HPLC Assay)	
Related Substances/Impurities (Same Complex HPLC Assay, no addn'l stds)	
Hydrazine (Complex HPLC Assay)	
pH	
SG1 Diacid	
Particulate Matter (HIAC)	C
Sterility	
Bacterial Endotoxin (Gel Clot LAL)	D

Study Activities and Use Fees

Thermal Chamber Use Fee (for 1 basket of samples per storage condition)	X
Sample labeling (for Sterile products)	
Stability framework, protocol, and database creation	Y
SLIM Database Reports	

Storage Conditions and Activities	Intervals in Months											Total
	0	1	3	6	9	12	18	24	36	48	60	
Administrative	XY	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	
40C/75%RH	A,C,D ⁽¹⁾	A	A	A								
25C/60%RH		A	A	A	A	A,C	A	A,C	A	A	A	
5C		A	A	A	A	A,C	A	A,C	A,C	A,C	A,C	

⁽¹⁾ Assumed that Product Release Data will be used for the initial (T0) timepoint.

Price per Time point: \$ 10,800 \$ 9,700 \$ 9,700 \$ 9,700 \$ 8,300 \$ 8,900 \$ 8,300 \$ 8,900 \$ 8,800 \$ 8,800 \$ 8,800 \$ 100,700

Assumptions:

- 1) Analytical activities include the cost of reasonable and customary expendables associated with performing test methods, such as USP reference standards, solvents, and
- 2) Assumed DSM has all required equipment and expertise to perform required tests (as listed in the bid).
- 3) Assumed that Product Release Data would be used for the initial (T0) timepoint.
- 4) The sample allocations provided by Siga are not sufficient to support these studies.

Attachment B



ST-246 Clinical Batch Proposal

**Issued July 20, 2012
Version 8
for
SIGA Technologies, Inc.**

**Submitted By:
Diane Lever, Sr. Account Director/Business Development**

DSM Pharmaceuticals, Inc.
5900 Martin Luther King Jr. Highway
Greenville, NC 27834
www.dsmpharmaceuticalproducts.com

SIGA-ST-246

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- 1.1 Introduction
- 1.2 Proposal Summary
- 1.3 Terms of Supply

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- 2.1 Standard Project Assumptions
- 2.2 Contacts Listing

Attachments

- Attachment 1: Capital
- Attachment 2: Stability

Section 1: Executive Summary

1.1 Introduction

DSM Pharmaceuticals Inc. (DPI) is a leading provider of product Development, Manufacturing and Packaging services to global Pharmaceutical & Biotechnology companies. Through continuous Investment and Innovation, and with a commitment to Quality and Security of Supply, DPI strives to be the preferred partner of choice for the production of sterile & solid dosage forms. Delivering outstanding service & value to our customers, combined with our experience, relevant expertise and state-of-the-art equipment, makes us uniquely qualified to support product success.

DPI Delivers **Total Value** to its Customers:

- A **Sustainable** Business Partner
 - 100 Year Legacy of Royal DSM N.V.
 - World Leader on the Dow Jones Sustainability Index
 - Solid, Independent Financial Position
- A **Compelling Facility**
 - 1.5MM square feet over 640 acres
 - All service offerings based at one site
 - DSM capital investment of \$176MM since 2001
- An **Unparalleled Level of Experience**
 - Continuous operations in Greenville, NC for 40 years
 - Development, Manufacturing & Packaging services
 - Average staff tenure of 14 years
 - Repeatedly launch 10 or more new products annually
- **Premium Quality** Systems & Processes
 - Fully-integrated, computerized systems such as SAP, Documentum and Trackwise
 - Proprietary, oracle-based software system called iMost, for planning, scheduling and as a data hub, offering complete visibility into production status
- Demonstrated **Regulatory Excellence**
 - Extraordinary international agency audit history
 - More than 90% of PAIs waived since 2007
- **DEA Licensed** Facility
 - Licensed to manufacture CII-CV products

DSM Pharmaceuticals, Inc. appreciates the opportunity to propose clinical trial material (CTM) pricing to **SIGA Technologies, Inc.** for **ST-246**, and looks forward to further discussions to ensure we fully address your team's specific needs. We are confident that DPI offers unique advantages, making us the best CMO option. DPI's leadership position in the CMO sector is driven by collaborative partnerships, with the goal of mutual success.

DSM Pharmaceuticals, Inc. wishes to thank SIGA Technologies, Inc. for their consideration of our experience, expertise and Commitment to Excellence.

1.2 Proposal Summary

This proposal is focused on providing pricing for early phase clinical liquid ST-246 product utilizing a 30cc qualified container closure system on DSM's CTM line for SIGA Technologies, Inc.

1.3 Terms of Supply

1.3.1 CTM Price

Batch Type	Batch Size Vials	Per Batch Price	Tiers
ST-246 (30mL vial) CTM	~1,800	\$80,000	1-2 CTM batches
ST-246 (30mL vial) CTM	~1,800	\$75,000	3-4 CTM batches
ST-246 (30mL vial) CTM	~1,800	\$70,000	> 4 CTM batches

1. Price includes manufacturing, filling and bulk packaging into shippers.
2. The following testing and QA release is included in price above:
Appearance, pH, Assay/Related Substances by HPLC, Hydrazine, Total Impurities, Particulate Matter, Osmolality, PFB, Sterility, and BET.
Assumes DSM will ship samples to Ricerca for contract testing of SG1Diacid.
3. Price does not include the active ingredient or Kleptose, to be provided by SIGA Technologies, Inc.
4. Assumes a 22mL fill volume.
5. The container/closure to be used is a 30cc vial within DSM inventory. This vial and stopper is qualified on the CTM Line. DSM component item numbers: 30cc vial #321649, 20mm Stopper # 005305, Cap # 013329.
6. Assumes product does not require nude vial labeling.
7. Rescheduling fee of \$10,000 will be charged for changes within the 30-day firm zone. A CTM agreement that also contains quality terms will be required prior to manufacture of CTM batches.

CTM Transfer Services and Activities

Description	Pricing
Project Management Support Analytical Services -Develop and validate BET, Bioburden and Sterility methods -Analytical method transfers: <u>IV Formulation Product:</u> <ul style="list-style-type: none"> • Validate and transfer Assay and Related Substances (SG2, 4TFMBA, ST-246 Exo Isomer, Impurity A, SG1 hydrazide) by HPLC. • Trial alternative detection methods/techniques for SG1 Diacid • Validate and transfer Hydrazine • Verify Appearance of solution, pH, Particulate matter, Osmolality <u>Lyophilized Product (for development batch on stability):</u> Initial stability data for Assay/Related Substances and Hydrazine will be generated using analytical methods that will not be fully validated.	\$148,900
Validation Services -Validation CTM Line Assessment and Assessment Summary	\$8,000
Contract Lab testing to release Kleptose at DSM. Assumes 4 batches of Kleptose. Fee of \$8,400 per Kleptose batch.	\$33,600
Required set up activities for Kleptose. Full commercial set up is required since DSM will contract the testing. <ul style="list-style-type: none"> • Create an RMIR for material • Create an analytical standard for testing material • Create a sampling protocol • Create LIMS template 	\$12,400
Total:	\$202,900
ID test for final packaged CTM samples. (Optional)	\$2,400 per sample (Optional)

Batches:

Media Fills - not required due to change to DSM qualified 30cc liquid vial/stopper combination on the CTM line.	\$0
Lyo and Liquid Development Batch Manufacture (1) 50L batch split between Lyo and Liquid to support stability. Note: will not fill all of bulk into vials. - Assumes compounding in the CTM suite. Hand fill and lyophilize approximately 378 vials in the non-GMP area of Bldg 8 utilizing the 8 sq. ft. freeze dryer. - Assumes approximately a 50-60 hour lyo cycle. - For the Lyo portion - assumes a 50cc vial # 400015, 20mm stopper #005677 and Overseal # 013329. - Assumes ~600 vials to support the liquid formulation study. For the Liquid portion – assumes a 30cc vial	\$50,600
Liquid Placebo Batch (1) batch for Human Use (~1,800 vials). Must be completed in CTM Suite since a Human Use batch. Price includes set up of an analytical standard to support testing and stability.	See 1.3.1 of this proposal for batch pricing \$80,000
Liquid Active Batch (1) batch for Human Use (~1,800 vials) Must be completed in CTM Suite since for Human Use batch.	See 1.3.1 of this proposal for batch pricing \$80,000
Total:	\$210,600

Capital Estimate: \$26,840 See attachment #1 for additional information.

Stability Estimate: \$335,600

Study	Price
50cc Vial – One Lyo Development batch on stability	\$116,800
30cc Vial – One Liquid Development batch on stability	\$57,600
30cc Vial - One Liquid Active CTM batch on stability	\$89,500
30cc Vial - One Liquid Placebo CTM batch on stability	\$45,200
Photostability study	\$26,500

1. Testing based on ICH guidelines.
2. See Attachment #2 for stability protocols and time point pricing.

Section 2: Project Strategy

2.1 Project Scope

This project is intended to execute the clinical manufacturing transfer of ST-246 for SIGA to the CTM line in Steriles North. DSM will supply CTM product to SIGA. The strategy for executing this project is as follows:

SIGA's ST-246 is an aseptically filled liquid product in final dosage form. The product is intended for distribution in US clinical trials. The project requires at minimum the scope of work outlined in this proposal to qualify DSM as a site of manufacture for ST-246 CTM material.

The project's scope involves manufacturing, filling, and release of ST-246 CTM product and is therefore developmental in nature. As such, issues and unexpected outcomes are anticipated for which ongoing technical support by DSM may be required. Any unanticipated technical support is out of scope for this proposal.

In all aspects of this project, DSM is responsible for adhering to appropriate GMPs and sound defensible development or transfer plans which will be acceptable, in DSM's opinion, to current regulatory expectations.

2.2 CTM Strategy

2.2.1 Scope/ Contract Finalization

Following proposal approval, a CTM agreement that also contains quality terms will be approved by both organizations. After the CTM agreement is in place, the project will be initiated. Payment terms will be 14 days from invoice date.

2.2.2 Initial Process Feasibility/Transfer Activities

The CTM area Technical Representative will review the technical documents submitted by SIGA for the manufacture, filling and testing of ST-246. Documents to be prepared by DSM, with SIGA input and review should include formula and manufacturing instructions/batch record. SIGA will provide documents for API/BDS and product storage requirements.

Analytical services include:

- Set up Analytical standard for the API, Kleptose, IV Formulation and Lyo development Products
- Set up Analytical standard for the IV Formulation placebo batch
- Develop and Validate BET, Bioburden and Sterility Methods
- Assumes Appearance and ID on API.

Contract Lab testing to release Kleptose at DSM. Assumes 1 batch of Kleptose and fee applies to each batch if multiple batches are required.

Analytical method validation and transfers:

IV Formulation Product:

- Validate and transfer Assay and Related Substances (SG2, 4TFMBA, ST-246 Exo Isomer, Impurity A, SG1 hydrazide) by HPLC.
- Trial alternative detection methods/techniques for SG1 Diacid
- Validate and transfer Hydrazine
- Verify Appearance of solution, pH, Particulate matter and Osmolality.

The following testing and QA release is included in batch pricing: Appearance, Appearance of solution, pH, Assay/Related Substances by HPLC, Hydrazine, Total Impurities, Particulate Matter, Osmolality, PFB, Sterility, and BET.

Assumes DSM will ship samples to contract lab, Ricerca, for contract testing of SG1 Diacid.

2.2.3 CTM Services

CTM Batch – Multiple CTM batches are included in this proposal. All in process and finished product testing will be required.

One 30cc vial size - Liquid Development batch for stability only.
One 50cc vial size - Lyo Development batch for stability only.
One 30cc vial size - Liquid Placebo CTM batch
One 30cc vial size - Liquid Active CTM batch

2.2.4 Validation Services

Validation Services include a CTM Line Assessment and Assessment Summary.

Procedures for cleaning will be TOC for any equipment that is not disposable utilizing the DSM cleaning model. All filler product contact equipment is disposable.

2.2.5 Regulatory Services

DSM regulatory support activities are considered optional and are out of the scope of this proposal.

2.2.6 DSM Quality Assurance

DSM's Quality Assurance department will act as a compliance consultant and provide Quality oversight for adherence to regulatory requirements. This will include but not limited to the following: Documentation, Validation, and Investigations.

SIGA understands that DSM has considerable regulatory and compliance responsibility associated with this project. In all aspects of this project, DSM is responsible for adhering to appropriate GMPs and sound defensible development plans which will be acceptable, in DSM's opinion, to current regulatory expectations. DSM will not knowingly execute (or bypass) activities which are inconsistent with

the above or which will jeopardize DSM's regulatory status. At a minimum DSM's applicable Quality Systems must be met.

2.3 Standard Project Assumptions

2.3.1 General Assumptions

1. Project requires completion of a MSDS and assessment of Safety issues, potential environmental concerns, and waste disposal procedures, as appropriate, for this project. This proposal assumes the Chemical Health Protection rating is a CAT3 or less.
2. The API and excipients will be provided by the customer unless they are DSM current standard materials.
3. Customer will provide sufficient quantities of material for qualification of the BET and Sterility testing to be performed at DSM.
4. All materials supplied by SIGA Technologies, Inc. will arrive at DSM with appropriate documentation to be received into DSM's inventory, a certificate of analysis, certificate of compliance and chain of custody.
5. Standard DSM Documentation will be used for the filling process using the customer's critical parameters and process.
6. Storage condition of API and finished product will be controlled room temperature with ambient humidity.
7. A double sterile filtration will be performed.
8. Fill weight checks are part of the standard DSM process.
9. Inspection of the vials will include inspection for container closure and foreign matter (no product or cosmetic inspection). No retain samples will be taken or held at DSM.
10. Batch records review will be performed by DSM before QA release of the CTM batch. However upon request, product may be shipped under conditional status.
11. All unused material supplied by the customer will be returned or destroyed within 90 days of production if no additional demand is required.
12. Shipping of product, product samples, and documentation will be freight collect FOB Greenville. DSM will tender the materials to an approved carrier.

2.3.2 Optional Services Upon Request

- Regulatory Affairs documentation support.

2.3.3 Excluded materials or activities

Controlled or Cytotoxic substances are excluded materials from this production area.

1. DSM does not provide CTM labeling or final packaging at this time.
2. Phase III services are available and manufactured on commercial equipment.
3. Temperature controlled processing is not available on this equipment. Temperature controlled storage of API and finished product is available for specific temperature ranges.

2.4 Contacts Listing

Primary DSM contacts for this proposal are as follows:

Table 1: Contacts

Name	Phone number	Role	E-mail address
Diane Lever	510-524-2852	Sr. Account Director/Business Development	Diane.Lever@DSM.com
Ray Braxton	252-707-7240	CTM Manager-Technical Lead	Ray.braxton@DSM.com
Jennifer Adams	252-707-2049	Business Services	Jennifer.Adams@DSM.com

Attachment 1: Capital Estimate

Siga Technologies, Inc. (ST-246) Capital Estimate for CTM Line - North	
DESCRIPTION	BUDGET
50 ml vial size 20mm stopper, 25 ml fill - Lyo product	AMOUNT
EQUIPMENT	
Washer change parts (50 ml vial)	8,000
Misc. Tubing & Fittings and instruments	5,000
Filler change parts (50 ml vial)	8,000
FREIGHT	700
TAXES	700
ENGINEERING	2,000
Subtotal	24,400
CONTINGENCY @ 10%	2,440
Total	\$26,840
Change parts have ~6 to 8 week leadtime.	

Attachment 2: – Stability Protocols – (see next 5 pages)

Siga Technologies

ST-246 214 mg/vial

Package Presentation: 30 mL vial

One Storage Orientation

One CTM batch (liquid product) will be placed on stability (one stability study)

Study Attributes	Protocol Code
Physical Exam (Product Appearance of Liquid)	A
Active Potency (Complex HPLC Assay)	
Related Substances/Impurities (Same Complex HPLC Assay, no addn'l stds)	
Hydrazine (Complex HPLC Assay)	
pH	
SG1 Diacid	C
Particulate Matter (HIAC)	
Sterility	D
Bacterial Endotoxin (Gel Clot LAL)	

Study Activities and Use Fees

Thermal Chamber Use Fee (for 1 basket of samples per storage condition)	X
Sample labeling (for Sterile products)	
Stability framework, protocol, and database creation	Y
SLIM Database Reports	

Storage Conditions and Activities	Intervals in Months									
	0	1	3	6	9	12	18	24	36	48
Administrative	XY	Y	Y	Y	Y	Y	Y	Y	Y	Y
40C/75%RH	A,C,D ⁽¹⁾	A	A	A,C,D						
25C/60%RH		A	A	A,C	A	A,C,D	A	A,C	A	A
5C		A	A	A,C	A	A,C,D	A	A,C	A	A

⁽¹⁾ Assumed that Product Release Data will be used for the initial (T0) timepoint.

Price per Time point:	\$ 9,700	\$ 9,700	\$ 9,700	\$ 11,600	\$ 7,000	\$ 10,600	\$ 8,300	\$ 8,900	\$ 7,000	\$ 7,000	\$ 89,500
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Assumptions:

1) Analytical activities include the cost of reasonable and customary expendables associated with performing test methods, such as USP reference standards, solvents, and common HPLC columns, etc. However, some analyses may utilize especially numerous, particularly costly, or short-lived expendables, including limitedly available or expensive reference standards/markers as well as specialized, fragile, or short-lived HPLC columns, and other such "uncustomary" items. These limitedly available or atypically costly analytical items are not included in the analytical costs for this project and will either be provided by the client or billed to the client incrementally to the proposal price.

2) Assumed DSM has all required equipment and expertise to perform required tests (as listed in the bid).

3) Assumed that Product Release Data would be used for the initial (T0) timepoint.

4) The sample allocations provided by Siga are not sufficient to support these studies.

Siga Technologies
ST-246 214 mg/vial
Package Presentation: 30 mL vial - Liquid formulation
One Storage Orientation
One Placebo CTM batch placed on stability (one stability study)

Study Attributes	Protocol Code
Physical Exam (Product Appearance)	A
Active Potency (Complex HPLC Assay - Absence of Active)	A
Particulate Matter (HIAC)	C
Sterility	D
Bacterial Endotoxin (Gel Clot LAL)	D

Study Activities and Use Fees	
Thermal Chamber Use Fee (for 1 basket of samples per storage condition)	X
Sample labeling (for Sterile products)	X
Stability framework, protocol, and database creation	X
SLIM Database Reports	Y

Storage Conditions and Activities	Intervals in Months								
	0	1	3	6	9	12	18	24	36
Administrative	XY	Y	Y	Y	Y	Y	Y	Y	Y
40C/75%RH	A,B,C,D,I ⁽¹⁾	A	A	A,C,D					
25C/60%RH		A	A	A,C	A	A,C,D	A	A	A
5C		A	A	A,C	A	A,C,D	A	A	A

⁽¹⁾ Assumed that Product Release Data will be used for the initial (T0)

Price per Time point: \$ 8,900 \$ 3,700 \$ 3,700 \$ 5,600 \$ 3,500 \$ 5,800 \$ 3,500 \$ 3,500 \$ 3,500

Assumptions:

- 1) Analytical activities include the cost of reasonable and customary expendables associated with performing test methods, such as USP reference standards, solvents, and common HPLC columns, etc. However, some analyses may utilize especially numerous, particularly costly, or short-lived expendables, including limitedly available or expensive reference standards/markers as well as specialized, fragile, or short-lived HPLC columns, and other such "uncustomary" items. These limitedly available or atypically costly analytical items are not included in the analytical costs for this project and will either be provided by the client or billed to the client incrementally to the proposal price.
- 2) Assumed DSM has all required equipment and expertise to perform required tests (as listed in the bid).
- 3) Assumed that Product Release Data would be used for the initial (T0) timepoint.
- 4) The sample allocations provided by Siga are not sufficient to support these studies.

Siga Technologies

ST-246 214 mg/vial

Package Presentation: 30 mL vial

One Storage Orientation

One Development batch (liquid product) will be placed on stability (one stability study)

Study Attributes	Protocol Code
Physical Exam (Product Appearance of Liquid)	A
Active Potency (Complex HPLC Assay)	
Related Substances/Impurities (Same Complex HPLC Assay, no addn'l stds)	
Hydrazine (Complex HPLC Assay)	
pH	
SG1 Diacid (Outsourced)	C
Particulate Matter (HIAC)	

Study Activities and Use Fees

Thermal Chamber Use Fee (for 1 basket of samples per storage condition)	X
Sample labeling (for Sterile products)	
Stability framework, protocol, and database creation	Y
SLIM Database Reports	

Storage Conditions and Activities	Intervals in Months									
	0	1	3	6	9	12	18	24	36	48
Administrative	XY	Y	Y	Y	Y	Y	Y	Y	Y	Y
40C/75%RH	A,C ⁽¹⁾	A,C	A,C	A,C						
25C/60%RH		A	A	A	A	A,C	A	A,C	A	A
5C		A	A	A	A	A,C	A	A,C	A	A

⁽¹⁾ Assumed that Product Release Data will be used for the initial (T0) timepoint.

Price per Time point: \$ 9,300 \$ 6,700 \$ 6,700 \$ 6,700 \$ 4,200 \$ 5,700 \$ 4,200 \$ 5,700 \$ 4,200 \$ 4,200 \$ 57,600

Assumptions:

1) Analytical activities include the cost of reasonable and customary expendables associated with performing test methods, such as USP reference standards, solvents, and common HPLC columns, etc. However, some analyses may utilize especially numerous, particularly costly, or short-lived expendables, including limitedly available or expensive reference standards/markers as well as specialized, fragile, or short-lived HPLC columns, and other such "uncustomary" items. These limitedly available or atypically costly analytical items are not included in the analytical costs for this project and will either be provided by the client or billed to the client incrementally to the proposal price.

2) Assumed DSM has all required equipment and expertise to perform required tests (as listed in the bid).

3) Assumed that Product Release Data would be used for the initial (T0) timepoint.

4) The sample allocations provided by Siga are not sufficient to support these studies.

Siga Technologies

ST-246 214 mg/vial

Package Presentation: 50 mL vial (Lyo product)

One Storage Orientation

One Development batch placed on stability (one stability study)

Study Attributes

Protocol Code

Physical Exam (Lyo Product Appearance)	A
Physical Exam (Reconstituted Product Appearance)	
Active Potency (Complex HPLC Assay)	
Related Substances/Impurities (Same Complex HPLC Assay, no addn'l stds)	
Hydrazine (Complex HPLC Assay)	
pH after reconstitution	
Dissolution/Reconstitution Time	
SG1 Diacid (Outsourced)	
Moisture Content (KF)	
Particulate Matter (HIAC)	C

Study Activities and Use Fees

Thermal Chamber Use Fee (for 1 basket of samples per storage condition)	X
Sample labeling (for Sterile products)	
Stability framework, protocol, and database creation	Y
SLIM Database Reports	

Storage Conditions and Activities	Intervals in Months									
	0	1	3	6	9	12	18	24	36	48
Administrative	XY	Y	Y	Y	Y	Y	Y	Y	Y	Y
40C/75%RH	A,C ⁽¹⁾	A	A	A,C						
25C/60%RH			A	A	A	A,C	A	A,C	A	A
5C ⁽²⁾			A	A	A	A,C	A	A,C	A	A
timepoint.										

Price per Time point: \$ 9,700 \$ 9,600 \$ 13,000 \$ 14,100 \$ 11,300 \$ 12,400 \$ 11,300 \$ 12,800 \$ 11,300 \$ 11,300 \$ 116,800

Assumptions:

1) Analytical activities include the cost of reasonable and customary expendables associated with performing test methods, such as USP reference standards, solvents, and common HPLC columns, etc. However, some analyses may utilize especially numerous, particularly costly, or short-lived expendables, including limitedly available or expensive reference standards/markers as well as specialized, fragile, or short-lived HPLC columns, and other such "uncustomary" items. These limitedly available or atypically costly analytical items are not included in the analytical costs for this project and will either be provided by the client or billed to the client incrementally to the proposal price.

2) Assumed DSM has all required equipment and expertise to perform required tests (as listed in the bid).

3) Assumed that Product Release Data would be used for the initial (T0) timepoint.

4) The sample allocations provided by Siga are not sufficient to support these studies.

Siga

ST-246 (10 mg/mL)

Photostability per ICH Option 2 on the IV Formulation (one stability study)

Study Attributes	Protocol Code
Physical Exam (Product Appearance of Liquid)	A
Active Potency (Complex HPLC Assay)	
Related Substances/Impurities (Same Complex HPLC Assay, no addn'l stds)	
Hydrazine (Complex HPLC Assay)	
pH	
SG1 Diacid (Outsourced)	
Particulate Matter (HIAC)	

Study Activities and Use Fees

Thermal Chamber Use Fee (for 1 basket of samples per storage condition)	X
Sample labeling (for Sterile products)	
Stability framework, protocol, and database creation	
Light Chamber Use Fee	
SLIM Database Reports	Y

Storage Conditions and Activities	Intervals in Months		Total
	0	0.5	
Administrative	XY	Y	
ICH Option 2 Photostability Chamber (Unpackaged in Open Dish)		A ⁽¹⁾	
ICH Option 2 Photostability Chamber (Unpackaged in Open Dish - Dark Control)		A ⁽¹⁾	
ICH Option 2 Photostability Chamber (in Primary Packaging)		A ⁽¹⁾	
ICH Option 2 Photostability Chamber (in Primary Package - Dark Control)		A ⁽¹⁾	
⁽¹⁾ Treatment will likely not coincide with other testing for other storage stations			
⁽²⁾ Tested only if Open Dish UV/Fluorescent Chamber condition fails			

Price per Time point: \$ 7,200 \$ 19,300 \$ 26,500

Assumptions:

- 1) Photostability will be performed per ICH Option 2.
- 2) The open dish exposure and primary packaging samples will be exposed and tested simultaneously.
- 3) Assumed photostability would not coincide with any other testing.
- 4) Assumed that we would only perform photostability on the IV formulation (demo batch).
- 5) Assumed that we have enough samples to perform the photostability of the IV demo batch.

**Exhibit F to the
Services Agreement
Dated 12 January 2012**

Statement of Work #6

This Exhibit details the services that Company will provide to SIGA. The services under this Exhibit shall be conducted under and subject to the terms and conditions of the Services Agreement between SIGA and Company, hereinafter ("SA").

Scope of Services

The Scope of Services is applicable to **the manufacture of 1 development batch (~378 vials) plus required line equipment and one development batch on stability through the 3 month interval as presented in ST-246 Clinical Batch Proposal, Version 4, dated 26 March 2012 (see attachment A).** The remaining stability intervals will be covered under a separate Exhibit and Purchase Order.

Payment Terms

Total charges for professional service fees and direct expenses will not exceed **\$104,990**. Upon the execution of this Exhibit, and unless the parties otherwise agree, Company shall invoice SIGA in the following manner:

CTM line equipment (\$28,490) – upon receipt of a Purchase Order from SIGA;
Manufacture of 1 development batch (~348 vials) (\$46,600) – on a monthly basis at the time of Company's initiation;
Stability through 3 months (\$10,500, \$9,700, \$9,700) – at each interval after the stability report is issued.

SIGA agrees to pay to Company according to the terms set forth in Paragraph 4 of the above-referenced SA.

Term of this Exhibit

Services will commence upon execution of this Exhibit and will be completed by December 31, 2012.

SIGA Technologies, Inc.

BY: *Dennis E. Hruby*
NAME: Dennis E. Hruby, Ph.D.
TITLE: Chief Scientific Officer

DATE: *05 Apr 2012*

DSM Pharmaceuticals, Inc.

BY: *Dawn L. Parks*
NAME: *Dawn L. Parks*
TITLE: *Sr. V.P. Marketing & Sales*

DATE: *5 Apr 2012*



ST-246 Clinical Batch Proposal

**Issued March 26, 2012
Version 4 - Correction
for
SIGA Technologies, Inc.**

**Submitted By:
Diane Lever, Sr. Account Director/Business Development**

DSM Pharmaceuticals, Inc.
5900 Martin Luther King Jr. Highway
Greenville, NC 27834
www.dsmpharmaceuticalproducts.com

SIGA-ST-246

CONTENTS

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- 1.1 Introduction
- 1.2 Proposal Summary
- 1.3 Terms of Supply

Section 2: Project Strategy

- 2.1 Standard Project Assumptions
- 2.2 Contacts Listing

Attachments

- Attachment 1: Capital
- Attachment 2: Stability

Section 1: Executive Summary

1.1 Introduction

DSM Pharmaceuticals Inc. (DPI) is a leading provider of product Development, Manufacturing and Packaging services to global Pharmaceutical & Biotechnology companies. Through continuous Investment and Innovation, and with a commitment to Quality and Security of Supply, DPI strives to be the preferred partner of choice for the production of sterile & solid dosage forms. Delivering outstanding service & value to our customers, combined with our experience, relevant expertise and state-of-the-art equipment, makes us uniquely qualified to support product success.

DPI Delivers **Total Value** to its Customers:

- A **Sustainable** Business Partner
 - 100 Year Legacy of Royal DSM N.V.
 - World Leader on the Dow Jones Sustainability Index
 - Solid, Independent Financial Position
- A **Compelling Facility**
 - 1.5MM square feet over 640 acres
 - All service offerings based at one site
 - DSM capital investment of \$176MM since 2001
- An **Unparalleled Level of Experience**
 - Continuous operations in Greenville, NC for 40 years
 - Development, Manufacturing & Packaging services
 - Average staff tenure of 14 years
 - Repeatedly launch 10 or more new products annually
- **Premium Quality** Systems & Processes
 - Fully-integrated, computerized systems such as SAP, Documentum and Trackwise
 - Proprietary, oracle-based software system called iMost, for planning, scheduling and as a data hub, offering complete visibility into production status
- Demonstrated **Regulatory Excellence**
 - Extraordinary international agency audit history
 - More than 90% of PAIs waived since 2007
- **DEA Licensed** Facility
 - Licensed to manufacture CII-CV products

DSM Pharmaceuticals, Inc. appreciates the opportunity to propose clinical trial material (CTM) pricing to **SIGA Technologies, Inc.** for **ST-246**, and looks forward to further discussions to ensure we fully address your team's specific needs. We are confident that DPI offers unique advantages, making us the best CMO option. DPI's leadership position in the CMO sector is driven by collaborative partnerships, with the goal of mutual success.

DSM Pharmaceuticals, Inc. wishes to thank SIGA Technologies, Inc. for their consideration of our experience, expertise and Commitment to Excellence.

1.2 Proposal Summary

This proposal is focused on providing pricing for early phase clinical lyophilized ST-246 product utilizing a container closure system from DSM inventory, but it is not qualified on DSM's CTM line for SIGA Technologies, Inc.

1.3 Terms of Supply

1.3.1 CTM Price

Batch Type	Batch Size Vials	Per Batch Price	Tiers
ST-246 (50mL vial) CTM	~900	\$102,000	1 -2 CTM batches
ST-246 (50mL vial) CTM	~900	\$96,000	3-4 CTM batches
ST-246 (50mL vial) CTM	~900	\$89,000	> 4 CTM batches

- Price includes manufacturing, filling and bulk packaging into shippers.
- The following testing and QA release is included in price above:
Appearance, Water, Reconstitution time/appearance of solution, pH, Assay/Related Substances by HPLC, Hydrazine, Total Impurities, Particulate Matter, Osmolality, PFB, Sterility, and BET. Assumes DSM will ship samples to SIGA for contract testing of XRPD and SG1Diacid.
- Price does not include the active ingredient or Kleptose, to be provided by SIGA Technologies, Inc.
- Assumes a 25mL fill volume.
- Assumes lyophilization cycle is 75 hours.
- The container/closure to be used is a 50cc vial within DSM inventory. This vial and stopper requires validation on the CTM Line. DSM component item numbers: 50cc vial # 400015, 20mm stopper #005677 and Overseal # 013329.
- Assumes product does not require nude vial labeling.
- Rescheduling fee of \$10,000 will be charged for changes within the 30-day firm zone. A CTM agreement that also contains quality terms will be required prior to manufacture of CTM batches.

CTM Transfer Services and Activities

Description	Pricing
Project Management Support Analytical Services -Develop and Validate BET, Bioburden and Sterility Methods -Analytical method transfers: <u>Lyophilized Product:</u> <ul style="list-style-type: none"> Develop and Validate Water Content by KF. Validate and transfer Assay and Related Substances (SG2, 4TFMBA, ST-246 Exo Isomer, Impurity A, SG1 hydrazide) by HPLC. Trial alternative detection methods/techniques for SG1 Diacid Validate and transfer Hydrazine Verify Appearance of Lyophilized vial, Reconstitution time/Appearance of solution, pH, Particulate matter, Osmolality <u>Diluted Product:</u> <ul style="list-style-type: none"> Validate and transfer Assay and Related substances for Diluted sample. Validate and transfer Hydrazine for diluted sample. -Set up Analytical standard for the API and Product -Set up Analytical standard for Product to support stability testing -Assumes Appearance and ID on API and Kleptose.	\$188,300
Validation Services -Validation CTM Line Assessment and Assessment Summary -Vial Washing Validation -Vial Depyrogenation Validation -Stopper Validation	\$29,300
Water Batch (1) batch is required to test components and fill volume on the CTM line. (Siga requested to use Kleptose in this run, a non-issue per Lee Briley)	\$47,600
Media Fills (3) media fills are required due to the new largest vial on the CTM line. (\$78,700 per media fill)	\$236,100
Development Batch (1) batch Assumes compounding in the CTM suite. Hand fill and Lyo approximately 378 vials in Bldg 8 (Ron Pate's area) utilizing the 8 sq ft freeze dryer.	\$46,600
Placebo Batch (1) batch for Human Use (~900 vials) Must all be completed in CTM Suite since for Human Use batch. (Price includes set up of an analytical standard to support testing and stability.)	See 1.3.1 of this proposal for batch pricing
Active Batch (1) batch for Human Use (~900 vials) Must all be completed in CTM Suite since for Human Use batch.	See 1.3.1 of this proposal for batch pricing
Total:	\$547,900

ID test for final packaged CTM samples. (Optional)	\$2,400 per sample (Optional)
--	-------------------------------

Capital Estimate: \$28,490 See attachment #1 for additional information.

Stability Estimate: \$284,300

Study	Price
One Active CTM batch on stability	\$111,800
One Development batch on stability	\$111,800
One Placebo CTM batch on stability	\$60,700

1. Testing based on ICH guidelines.
2. See Attachment #2 for stability protocols and time point pricing.

Section 2: Project Strategy

2.1 Project Scope

This project is intended to execute the clinical manufacturing transfer of ST-246 for SIGA to the CTM line in Steriles North. DSM will supply CTM product to SIGA. The strategy for executing this project is as follows:

SIGA's ST-246 is an aseptically filled, lyophilized product in final dosage form. The product is intended for distribution in US clinical trials. The project requires at minimum the scope of work outlined in this proposal to qualify DSM as a site of manufacture for ST-246 CTM material.

The project's scope involves manufacturing, filling, and release of ST-246 CTM product and is therefore developmental in nature. As such, issues and unexpected outcomes are anticipated for which ongoing technical support by DSM may be required. Any unanticipated technical support is out of scope for this proposal.

In all aspects of this project, DSM is responsible for adhering to appropriate GMPs and sound defensible development or transfer plans which will be acceptable, in DSM's opinion, to current regulatory expectations.

2.2 CTM Strategy

2.2.1 Scope/ Contract Finalization

Following proposal approval, a CTM agreement that also contains quality terms will be approved by both organizations. After the CTM agreement is in place, the project will be initiated. Payment terms will be 14 days from invoice date.

2.2.2 Initial Process Feasibility/Transfer Activities

The CTM area Technical Representative will review the technical documents submitted by SIGA for the manufacture, filling and testing of ST-246. Documents to be provided by SIGA should include formula and manufacturing instructions/batch record, API/BDS and product storage requirements.

Analytical services include:

- Set up Analytical standard for the API, Kleptose and Product
- Set up Analytical standard for the placebo batch
- Develop and Validate BET, Bioburden and Sterility Methods
- Assumes Appearance and ID on API and Kleptose.

Analytical method transfers:

Lyophilized Product:

- Develop and Validate Water Content by KF.
- Validate and transfer Assay and Related Substances (SG2, 4TFMBA, ST-246 Exo Isomer, Impurity A, SG1 hydrazide) by HPLC.
- Trial alternative detection methods/techniques for SG1 Diacid
- Validate and transfer Hydrazine
- Verify Appearance of Lyophilized vial, Reconstitution time/Appearance of solution, pH, Particulate matter and Osmolality.

Diluted Product:

- Validate and transfer Assay and Related substances for Diluted sample.

- Validate and transfer Hydrazine for diluted sample.

The following testing and QA release is included in batch pricing:
Appearance, Water, Reconstitution time/appearance of solution, pH,
Assay/Related Substances by HPLC, Hydrazine, Total Impurities,
Particulate Matter, Osmolality, PFB, Sterility, and BET.

**Assumes DSM will ship samples to SIGA for contract testing of
XRPD and SG1 Diacid.**

2.2.3 CTM Services

CTM Batch – Multiple CTM batches are included in this proposal. All
in process and finished product testing will be required.

One Development batch
One Placebo CTM batch
Multiple Active CTM batches

2.2.4 Validation Services

Validation Services include a CTM Line Assessment and Assessment
Summary.

Procedures for cleaning will be TOC for any equipment that is not
disposable utilizing the DSM cleaning model. All filler product contact
equipment is disposable.

2.2.5 Regulatory Services

DSM regulatory support activities are considered optional and are out
of the scope of this proposal.

2.2.6 DSM Quality Assurance

DSM's Quality Assurance department will act as a compliance
consultant and provide Quality oversight for adherence to regulatory
requirements. This will include but not limited to the following:
Documentation, Validation, and Investigations.

SIGA understands that DSM has considerable regulatory and compliance responsibility associated with this project. In all aspects of this project, DSM is responsible for adhering to appropriate GMPs and sound defensible development plans which will be acceptable, in DSM's opinion, to current regulatory expectations. DSM will not knowingly execute (or bypass) activities which are inconsistent with the above or which will jeopardize DSM's regulatory status. At a minimum DSM's applicable Quality Systems must be met.

2.3 Standard Project Assumptions

2.3.1 General Assumptions

1. Project requires completion of a MSDS and assessment of Safety issues, potential environmental concerns, and waste disposal procedures, as appropriate, for this project. This proposal assumes the Chemical Health Protection rating is a **CAT3** or less.
2. The API and excipients will be provided by the customer unless they are DSM current standard materials.
3. Customer will provide sufficient quantities of material for qualification of the BET and Sterility testing to be performed at DSM.
4. All materials supplied by SIGA Technologies, Inc. will arrive at DSM with appropriate documentation to be received into DSM's inventory, a certificate of analysis, certificate of compliance and chain of custody.
5. Standard DSM Documentation will be used for the filling process using the customer's critical parameters and process.
6. Storage condition of API and finished product will be controlled room temperature with ambient humidity.
7. A double sterile filtration will be performed.
8. Fill weight checks are part of the standard DSM process.
9. Inspection of the vials will include inspection for container closure and foreign matter (no product or cosmetic inspection). No retain samples will be taken or held at DSM.
10. Batch records review will be performed by DSM before QA release of the CTM batch. However upon request, product may be shipped under conditional status.
11. All unused material supplied by the customer will be returned or destroyed within 90 days of production if no additional demand is required.

12. Shipping of product, product samples, and documentation will be freight collect FOB Greenville. DSM will tender the materials to an approved carrier.

2.3.2 Optional Services Upon Request

- Regulatory Affairs documentation support.

2.3.3 Excluded materials or activities

Controlled or Cytotoxic substances are excluded materials from this production area.

1. DSM does not provide CTM labeling or final packaging at this time.
2. Phase III services are available and manufactured on commercial equipment.
3. Temperature controlled processing is not available on this equipment. Temperature controlled storage of API and finished product is available for specific temperature ranges.

2.4 Contacts Listing

Primary DSM contacts for this proposal are as follows:

Table 1: Contacts

Name	Phone number	Role	E-mail address
Diane Lever	510-524-2852	Sr. Account Director/Business Development	Diane.Lever@DSM.com
Lee Briley	252-707-7230	CTM Manager-Technical Lead	Lee.Briley@DSM.com
Jennifer Adams	252-707-2049	Business Services	Jennifer.Adams@DSM.com

Attachment 1: Capital Estimate

SIGA Technologies, Inc. (ST-246) Capital Estimate for CTM Line - North	
DESCRIPTION	BUDGET
50 ml vial size 20mm stopper, 25 ml fill - Lyo product	AMOUNT
EQUIPMENT	
Washer change parts (50 ml vial)	8,000
Misc. Tubing & Fittings and instruments	5,000
Filler change parts (50 ml vial)	8,000
FREIGHT	700
TAXES	700
CRAFTS	
Production mechanic	1,500
ENGINEERING	2,000
Subtotal	25,900
CONTINGENCY @ 10%	2,590
Total	\$28,490

Change parts have ~6 to 8 week leadtime.

Attachment 2: – Stability Protocols – (see next 3 pages)

Siga Technologies

ST-246 250 mg/vial

Package Presentation: 50 mL vial

One Storage Orientation

One CTM batch placed on stability (one stability study)

Study Attributes	Protocol Code
Physical Exam (Lyo Product Appearance)	A
Physical Exam (Reconstituted Product Appearance)	
Active Potency (Complex HPLC Assay)	
Related Substances/Impurities (Same Complex HPLC Assay, no addn'l stds)	
Hydrazine (Complex HPLC Assay)	
pH after reconstitution	
Dissolution/Reconstitution Time	
Moisture Content (KF)	B
XRPD	C
Particulate Matter (HIAC)	
Sterility	D
Bacterial Endotoxin (Gel Clot LAL)	
Dilution Testing: Active Potency (Complex HPLC Assay)	
Dilution Testing: Related Substances/Impurities (Same Complex HPLC Assay, no addn'l stds)	
Dilution Testing: Hydrazine (Different Complex HPLC Assay)	

Study Activities and Use Fees

Thermal Chamber Use Fee (for 1 basket of samples per storage condition)	X
Sample labeling (for Sterile products)	
Stability framework, protocol, and database creation	
SLIM Database Reports	Y

Storage Conditions and Activities	Intervals in Months										Total
	0	1	3	6	9	12	18	24	36	48	
Administrative	XY	Y	Y	Y	Y	Y	Y	Y	Y	Y	
40C/75%RH	A,B,C,D ⁽¹⁾	A	A	A,B,C,D							
25C/60%RH		A	A	A,B,C	A	A,B,C,D	A,B	A,B	A	A	
5C ⁽²⁾		A	A	A,B,C	A	A,B,C,D	A,B	A,B	A	A	

⁽¹⁾ Assumed that Product Release Data will be used for the initial (T0)

Price per Time point: \$ 10,500 \$ 9,700 \$ 9,700 \$ 18,900 \$ 8,300 \$ 18,900 \$ 9,600 \$ 9,600 \$ 8,300 \$ 8,300 \$ 111,800

Assumptions:

- 1) Analytical activities include the cost of reasonable and customary expendables associated with performing test methods, such as USP reference standards, solvents, and common HPLC columns, etc. However, some analyses may utilize especially numerous, particularly costly, or short-lived expendables, including limitedly available or expensive reference standards/markers as well as specialized, fragile, or short-lived HPLC columns, and other such "uncustomary" items. These limitedly available or atypically costly analytical items are not included in the analytical costs for this project and will either be provided by the client or billed to the client incrementally to the proposal price.
- 2) Assumed DSM has all required equipment and expertise to perform required tests (as listed in the bid).
- 3) Assumed that Product Release Data would be used for the initial (T0) timepoint.
- 4) Assumed assay and related substances are determined from the same HPLC analysis.
- 5) The sample allocations provided by Siga are not sufficient to support these studies.
- 6) Hydrazine is determined from a different HPLC analysis.
- 7) The dilution study includes the following tests: Assay and Related Substances and Hydrazine.

Siga Technologies

ST-246 250 mg/vial

Package Presentation: 50 mL vial

One Storage Orientation

One Development batch placed on stability (one stability study)

Study Attributes	Protocol Code
Physical Exam (Lyo Product Appearance)	A
Physical Exam (Reconstituted Product Appearance)	
Active Potency (Complex HPLC Assay)	
Related Substances/Impurities (Same Complex HPLC Assay, no addn'l stds)	
Hydrazine (Complex HPLC Assay)	
pH after reconstitution	
Dissolution/Reconstitution Time	B
Moisture Content (KF)	
XRPD	C
Particulate Matter (HIAC)	
Sterility	D
Bacterial Endotoxin (Gel Clot LAL)	
Dilution Testing: Active Potency (Complex HPLC Assay)	
Dilution Testing: Related Substances/Impurities (Same Complex HPLC Assay, no addn'l stds)	
Dilution Testing: Hydrazine (Different Complex HPLC Assay)	

Study Activities and Use Fees

Thermal Chamber Use Fee (for 1 basket of samples per storage condition)	X
Sample labeling (for Sterile products)	
Stability framework, protocol, and database creation	Y
SLIM Database Reports	

Storage Conditions and Activities	Intervals in Months										Total
	0	1	3	6	9	12	18	24	36	48	
Administrative	XY	Y	Y	Y	Y	Y	Y	Y	Y	Y	
40C/75%RH	A,B,C,D ⁽¹⁾	A	A	A,B,C,D							
25C/60%RH		A	A	A,B,C	A	A,B,C,D	A,B	A,B	A	A	
5C ⁽²⁾		A	A	A,B,C	A	A,B,C,D	A,B	A,B	A	A	

⁽¹⁾ Assumed that Product Release Data will be used for the initial (T0)

Price per Time point: \$ 10,500 \$ 9,700 \$ 9,700 \$ 18,900 \$ 8,300 \$ 18,900 \$ 9,600 \$ 9,600 \$ 8,300 \$ 8,300 \$ 111,800

Assumptions:

- 1) Analytical activities include the cost of reasonable and customary expendables associated with performing test methods, such as USP reference standards, solvents, and common HPLC columns, etc. However, some analyses may utilize especially numerous, particularly costly, or short-lived expendables, including limitedly available or expensive reference standards/markers as well as specialized, fragile, or short-lived HPLC columns, and other such "uncustomary" items. These limitedly available or atypically costly analytical items are not included in the analytical costs for this project and will either be provided by the client or billed to the client incrementally to the proposal price.
- 2) Assumed DSM has all required equipment and expertise to perform required tests (as listed in the bid).
- 3) Assumed that Product Release Data would be used for the initial (T0) timepoint.
- 4) Assumed assay and related substances are determined from the same HPLC analysis.
- 5) The sample allocations provided by Siga are not sufficient to support these studies.
- 6) Hydrazine is determined from a different HPLC analysis.
- 7) The dilution study includes the following tests: Assay and Related Substances and Hydrazine.

DSM Pharmaceuticals, Inc.

Prices effective for the current Calendar year.

Siga Technologies
ST-246 250 mg/vial
Package Presentation: 50 mL vial
One Storage Orientation
One Placebo batch placed on stability (one stability study)

Study Attributes	Protocol Code
Physical Exam (Lyo Product Appearance)	A
Physical Exam (Reconstituted Product Appearance)	A
pH after reconstitution	A
Dissolution/Reconstitution Time	A
Active Potency (Complex HPLC Assay - Absence of Active)	I
Moisture Content (KF)	B
Particulate Matter (HIAC)	C
Sterility	D
Bacterial Endotoxin (Gel Clot LAL)	D

Study Activities and Use Fees

Thermal Chamber Use Fee (for 1 basket of samples per storage condition)	X
Sample labeling (for Sterile products)	X
Stability framework, protocol, and database creation	X
SLIM Database Reports	Y

Storage Conditions and Activities	Intervals in Months										Total
	0	1	3	6	9	12	18	24	36	48	
Administrative	XY	Y	Y	Y	Y	Y	Y	Y	Y	Y	
40C/75%RH	A,B,C,D,I ⁽¹⁾	A	A	A,B,C,D							
25C/60%RH		A	A	A,B,C	A	A,B,C,D	A,B	A,B	A	A	
5C		A	A	A,B,C	A	A,B,C,D	A,B	A,B	A	A	

⁽¹⁾ Assumed that Product Release Data will be used for the initial (T0)

Price per Time point: \$ 9,500 \$ 5,100 \$ 5,100 \$ 8,400 \$ 3,900 \$ 8,100 \$ 5,800 \$ 5,800 \$ 4,500 \$ 4,500 \$ 60,700

Assumptions:

- 1) Analytical activities include the cost of reasonable and customary expendables associated with performing test methods, such as USP reference standards, solvents, and common HPLC columns, etc. However, some analyses may utilize especially numerous, particularly costly, or short-lived expendables, including limitedly available or expensive reference standards/markers as well as specialized, fragile, or short-lived HPLC columns, and other such "uncustomary" items. These limitedly available or atypically costly analytical items are not included in the analytical costs for this project and will either be provided by the client or billed to the client incrementally to the proposal price.
- 2) Assumed DSM has all required equipment and expertise to perform required tests (as listed in the bid).
- 3) Assumed that Product Release Data would be used for the initial (T0) timepoint.
- 4) The sample allocations provided by Siga are not sufficient to support these studies.

**Amendment 1 to Exhibit F to the
Services Agreement
Dated 12 January 2012**

Statement of Work #6

This Amendment 1 hereby modifies and is made an integral part of Statement of Work #6 ("SOW #6") between SIGA Technologies, Inc. ("SIGA") and DSM Pharmaceuticals, Inc. ("Company"), which was entered into pursuant to the Master Services Agreement between SIGA and Company dated January 12, 2012 ("SA").

Under and subject to the terms and conditions of the SA, SIGA and Company wish to amend and revise the scope of the services set forth in SOW #6 as set forth below.

1. Revised Scope of Services

The Scope of Services is applicable to **the manufacture of (1) 50L development batch split between Lyo (~378 vials) and Liquid (~600 vials), corresponding stability studies (Lyo and liquid) through the 3 month interval and photostability plus required line equipment** and is revised as presented in **ST-246 Clinical Batch Proposal, Version 8**, dated **20 July 2012** attached hereto as Schedule A. The remaining stability intervals will be covered under a separate Exhibit and Purchase Order.

2. Fees and Payment Terms

Total charges for professional service fees and direct expenses will not exceed **\$158,940**. Upon the full execution of this Amendment 1, and unless the parties otherwise agree, Company shall invoice SIGA in the following manner:

CTM line equipment (\$26,840) – upon receipt of a Purchase Order from SIGA;
Manufacture of 1 development batch (\$50,600) – on a monthly basis at the time of initiation;

Stability through 3 months – Lyo (\$9,700, \$9,600, \$13,000) – at each interval after the stability report is issued.

Stability through 3 months – Liquid (\$9,300, \$6,700, \$6,700) – at each interval after the stability report is issued.

Photostability through 0.5 months (\$26,500) – upon issuance of the final photostability report.

SIGA agrees to pay to Company according to the terms set forth in Paragraph 4 of the above-referenced SA.

3. Term

Services will commence upon full execution of this Amendment 1 and will be completed by December 31, 2012.

This Amendment 1 is issued pursuant to and, upon its full execution by SIGA and Company, shall become incorporated into SOW #6, which is incorporated into the SA.

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SIGA Technologies, Inc.

BY: Dennis E. Hruby DATE: 30 Jul 2012
NAME: Dennis E. Hruby, Ph.D.
TITLE: Chief Scientific Officer

DSM Pharmaceuticals, Inc.

BY: Jenna L. Parks DATE: 6 Sep 2012
NAME: Jenna L. Parks
TITLE: President & Business Unit Director

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SCHEDULE A



ST-246 Clinical Batch Proposal

**Issued July 20, 2012
Version 8
for
SIGA Technologies, Inc.**

**Submitted By:
Diane Lever, Sr. Account Director/Business Development**

DSM Pharmaceuticals, Inc.
5900 Martin Luther King Jr. Highway
Greenville, NC 27834
www.dsmpharmaceuticalproducts.com

SIGA-ST-246

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- 1.1 Introduction
- 1.2 Proposal Summary
- 1.3 Terms of Supply

Section 2: Project Strategy

- 2.1 Standard Project Assumptions
- 2.2 Contacts Listing

Attachments

- Attachment 1: Capital
- Attachment 2: Stability

Section 1: Executive Summary

1.1 Introduction

DSM Pharmaceuticals Inc. (DPI) is a leading provider of product Development, Manufacturing and Packaging services to global Pharmaceutical & Biotechnology companies. Through continuous Investment and Innovation, and with a commitment to Quality and Security of Supply, DPI strives to be the preferred partner of choice for the production of sterile & solid dosage forms. Delivering outstanding service & value to our customers, combined with our experience, relevant expertise and state-of-the-art equipment, makes us uniquely qualified to support product success.

DPI Delivers **Total Value** to its Customers:

- A **Sustainable** Business Partner
 - 100 Year Legacy of Royal DSM N.V.
 - World Leader on the Dow Jones Sustainability Index
 - Solid, Independent Financial Position
- A **Compelling Facility**
 - 1.5MM square feet over 640 acres
 - All service offerings based at one site
 - DSM capital investment of \$176MM since 2001
- An **Unparalleled Level of Experience**
 - Continuous operations in Greenville, NC for 40 years
 - Development, Manufacturing & Packaging services
 - Average staff tenure of 14 years
 - Repeatedly launch 10 or more new products annually
- **Premium Quality** Systems & Processes
 - Fully-integrated, computerized systems such as SAP, Documentum and Trackwise
 - Proprietary, oracle-based software system called iMost, for planning, scheduling and as a data hub, offering complete visibility into production status
- Demonstrated **Regulatory Excellence**
 - Extraordinary international agency audit history
 - More than 90% of PAIs waived since 2007
- **DEA Licensed** Facility
 - Licensed to manufacture CII-CV products

DSM Pharmaceuticals, Inc. appreciates the opportunity to propose clinical trial material (CTM) pricing to **SIGA Technologies, Inc.** for **ST-246**, and looks forward to further discussions to ensure we fully address your team's specific needs. We are confident that DPI offers unique advantages, making us the best CMO option. DPI's leadership position in the CMO sector is driven by collaborative partnerships, with the goal of mutual success.

DSM Pharmaceuticals, Inc. wishes to thank SIGA Technologies, Inc. for their consideration of our experience, expertise and Commitment to Excellence.

1.2 Proposal Summary

This proposal is focused on providing pricing for early phase clinical liquid ST-246 product utilizing a 30cc qualified container closure system on DSM's CTM line for SIGA Technologies, Inc.

1.3 Terms of Supply

1.3.1 CTM Price

Batch Type	Batch Size Vials	Per Batch Price	Tiers
ST-246 (30mL vial) CTM	~1,800	\$80,000	1-2 CTM batches
ST-246 (30mL vial) CTM	~1,800	\$75,000	3-4 CTM batches
ST-246 (30mL vial) CTM	~1,800	\$70,000	> 4 CTM batches

1. Price includes manufacturing, filling and bulk packaging into shippers.
2. The following testing and QA release is included in price above:
Appearance, pH, Assay/Related Substances by HPLC, Hydrazine, Total Impurities, Particulate Matter, Osmolality, PFB, Sterility, and BET.
Assumes DSM will ship samples to Ricerca for contract testing of SG1Diacid.
3. Price does not include the active ingredient or Kleptose, to be provided by SIGA Technologies, Inc.
4. Assumes a 22mL fill volume.
5. The container/closure to be used is a 30cc vial within DSM inventory. This vial and stopper is qualified on the CTM Line. DSM component item numbers: 30cc vial #321649, 20mm Stopper # 005305, Cap # 013329.
6. Assumes product does not require nude vial labeling.
7. Rescheduling fee of \$10,000 will be charged for changes within the 30-day firm zone. A CTM agreement that also contains quality terms will be required prior to manufacture of CTM batches.

CTM Transfer Services and Activities

Description	Pricing
Project Management Support Analytical Services -Develop and validate BET, Bioburden and Sterility methods -Analytical method transfers: <u>IV Formulation Product:</u> <ul style="list-style-type: none"> • Validate and transfer Assay and Related Substances (SG2, 4TFMBA, ST-246 Exo Isomer, Impurity A, SG1 hydrazide) by HPLC. • Trial alternative detection methods/techniques for SG1 Diacid • Validate and transfer Hydrazine • Verify Appearance of solution, pH, Particulate matter, Osmolality <u>Lyophilized Product (for development batch on stability):</u> Initial stability data for Assay/Related Substances and Hydrazine will be generated using analytical methods that will not be fully validated.	\$148,900
Validation Services -Validation CTM Line Assessment and Assessment Summary	\$8,000
Contract Lab testing to release Kleptose at DSM. Assumes 4 batches of Kleptose. Fee of \$8,400 per Kleptose batch.	\$33,600
Required set up activities for Kleptose. Full commercial set up is required since DSM will contract the testing. <ul style="list-style-type: none"> • Create an RMIR for material • Create an analytical standard for testing material • Create a sampling protocol • Create LIMS template 	\$12,400
Total:	\$202,900
ID test for final packaged CTM samples. (Optional)	\$2,400 per sample (Optional)

Batches:

Media Fills - not required due to change to DSM qualified 30cc liquid vial/stopper combination on the CTM line.	\$0
Lyo and Liquid Development Batch Manufacture (1) 50L batch split between Lyo and Liquid to support stability. Note: will not fill all of bulk into vials. - Assumes compounding in the CTM suite. Hand fill and lyophilize approximately 378 vials in the non-GMP area of Bldg 8 utilizing the 8 sq. ft. freeze dryer. - Assumes approximately a 50-60 hour lyo cycle. - For the Lyo portion - assumes a 50cc vial # 400015, 20mm stopper #005677 and Overseal # 013329. - Assumes ~600 vials to support the liquid formulation study. For the Liquid portion – assumes a 30cc vial	\$50,600
Liquid Placebo Batch (1) batch for Human Use (~1,800 vials). Must be completed in CTM Suite since a Human Use batch. Price includes set up of an analytical standard to support testing and stability.	See 1.3.1 of this proposal for batch pricing \$80,000
Liquid Active Batch (1) batch for Human Use (~1,800 vials) Must be completed in CTM Suite since for Human Use batch.	See 1.3.1 of this proposal for batch pricing \$80,000
Total:	\$210,600

Capital Estimate: \$26,840 See attachment #1 for additional information.

Stability Estimate: \$335,600

Study	Price
50cc Vial – One Lyo Development batch on stability	\$116,800
30cc Vial – One Liquid Development batch on stability	\$57,600
30cc Vial - One Liquid Active CTM batch on stability	\$89,500
30cc Vial - One Liquid Placebo CTM batch on stability	\$45,200
Photostability study	\$26,500

1. Testing based on ICH guidelines.
2. See Attachment #2 for stability protocols and time point pricing.

Section 2: Project Strategy

2.1 Project Scope

This project is intended to execute the clinical manufacturing transfer of ST-246 for SIGA to the CTM line in Steriles North. DSM will supply CTM product to SIGA. The strategy for executing this project is as follows:

SIGA's ST-246 is an aseptically filled liquid product in final dosage form. The product is intended for distribution in US clinical trials. The project requires at minimum the scope of work outlined in this proposal to qualify DSM as a site of manufacture for ST-246 CTM material.

The project's scope involves manufacturing, filling, and release of ST-246 CTM product and is therefore developmental in nature. As such, issues and unexpected outcomes are anticipated for which ongoing technical support by DSM may be required. Any unanticipated technical support is out of scope for this proposal.

In all aspects of this project, DSM is responsible for adhering to appropriate GMPs and sound defensible development or transfer plans which will be acceptable, in DSM's opinion, to current regulatory expectations.

2.2 CTM Strategy

2.2.1 Scope/ Contract Finalization

Following proposal approval, a CTM agreement that also contains quality terms will be approved by both organizations. After the CTM agreement is in place, the project will be initiated. Payment terms will be 14 days from invoice date.

2.2.2 Initial Process Feasibility/Transfer Activities

The CTM area Technical Representative will review the technical documents submitted by SIGA for the manufacture, filling and testing of ST-246. Documents to be prepared by DSM, with SIGA input and review should include formula and manufacturing instructions/batch record. SIGA will provide documents for API/BDS and product storage requirements.

Analytical services include:

- Set up Analytical standard for the API, Kleptose, IV Formulation and Lyo development Products
- Set up Analytical standard for the IV Formulation placebo batch
- Develop and Validate BET, Bioburden and Sterility Methods
- Assumes Appearance and ID on API.

Contract Lab testing to release Kleptose at DSM. Assumes 1 batch of Kleptose and fee applies to each batch if multiple batches are required.

Analytical method validation and transfers:

IV Formulation Product:

- Validate and transfer Assay and Related Substances (SG2, 4TFMBA, ST-246 Exo Isomer, Impurity A, SG1 hydrazide) by HPLC.
- Trial alternative detection methods/techniques for SG1 Diacid
- Validate and transfer Hydrazine
- Verify Appearance of solution, pH, Particulate matter and Osmolality.

The following testing and QA release is included in batch pricing: Appearance, Appearance of solution, pH, Assay/Related Substances by HPLC, Hydrazine, Total Impurities, Particulate Matter, Osmolality, PFB, Sterility, and BET.

Assumes DSM will ship samples to contract lab, Ricerca, for contract testing of SG1 Diacid.

2.2.3 CTM Services

CTM Batch – Multiple CTM batches are included in this proposal. All in process and finished product testing will be required.

One 30cc vial size - Liquid Development batch for stability only.
One 50cc vial size - Lyo Development batch for stability only.
One 30cc vial size - Liquid Placebo CTM batch
One 30cc vial size - Liquid Active CTM batch

2.2.4 Validation Services

Validation Services include a CTM Line Assessment and Assessment Summary.

Procedures for cleaning will be TOC for any equipment that is not disposable utilizing the DSM cleaning model. All filler product contact equipment is disposable.

2.2.5 Regulatory Services

DSM regulatory support activities are considered optional and are out of the scope of this proposal.

2.2.6 DSM Quality Assurance

DSM's Quality Assurance department will act as a compliance consultant and provide Quality oversight for adherence to regulatory requirements. This will include but not limited to the following: Documentation, Validation, and Investigations.

SIGA understands that DSM has considerable regulatory and compliance responsibility associated with this project. In all aspects of this project, DSM is responsible for adhering to appropriate GMPs and sound defensible development plans which will be acceptable, in DSM's opinion, to current regulatory expectations. DSM will not knowingly execute (or bypass) activities which are inconsistent with

the above or which will jeopardize DSM's regulatory status. At a minimum DSM's applicable Quality Systems must be met.

2.3 Standard Project Assumptions

2.3.1 General Assumptions

1. Project requires completion of a MSDS and assessment of Safety issues, potential environmental concerns, and waste disposal procedures, as appropriate, for this project. This proposal assumes the Chemical Health Protection rating is a CAT3 or less.
2. The API and excipients will be provided by the customer unless they are DSM current standard materials.
3. Customer will provide sufficient quantities of material for qualification of the BET and Sterility testing to be performed at DSM.
4. All materials supplied by SIGA Technologies, Inc. will arrive at DSM with appropriate documentation to be received into DSM's inventory, a certificate of analysis, certificate of compliance and chain of custody.
5. Standard DSM Documentation will be used for the filling process using the customer's critical parameters and process.
6. Storage condition of API and finished product will be controlled room temperature with ambient humidity.
7. A double sterile filtration will be performed.
8. Fill weight checks are part of the standard DSM process.
9. Inspection of the vials will include inspection for container closure and foreign matter (no product or cosmetic inspection). No retain samples will be taken or held at DSM.
10. Batch records review will be performed by DSM before QA release of the CTM batch. However upon request, product may be shipped under conditional status.
11. All unused material supplied by the customer will be returned or destroyed within 90 days of production if no additional demand is required.
12. Shipping of product, product samples, and documentation will be freight collect FOB Greenville. DSM will tender the materials to an approved carrier.

2.3.2 Optional Services Upon Request

- Regulatory Affairs documentation support.

2.3.3 Excluded materials or activities

Controlled or Cytotoxic substances are excluded materials from this production area.

1. DSM does not provide CTM labeling or final packaging at this time.
2. Phase III services are available and manufactured on commercial equipment.
3. Temperature controlled processing is not available on this equipment. Temperature controlled storage of API and finished product is available for specific temperature ranges.

2.4 Contacts Listing

Primary DSM contacts for this proposal are as follows:

Table 1: Contacts

Name	Phone number	Role	E-mail address
Diane Lever	510-524-2852	Sr. Account Director/Business Development	Diane.Lever@DSM.com
Ray Braxton	252-707-7240	CTM Manager-Technical Lead	Ray.braxton@DSM.com
Jennifer Adams	252-707-2049	Business Services	Jennifer.Adams@DSM.com

Attachment 1: Capital Estimate

Siga Technologies, Inc. (ST-246) Capital Estimate for CTM Line - North	
DESCRIPTION	BUDGET
50 ml vial size 20mm stopper, 25 ml fill - Lyo product	AMOUNT
EQUIPMENT	
Washer change parts (50 ml vial)	8,000
Misc. Tubing & Fittings and instruments	5,000
Filler change parts (50 ml vial)	8,000
FREIGHT	700
TAXES	700
ENGINEERING	2,000
Subtotal	24,400
CONTINGENCY @ 10%	2,440
Total	\$26,840
Change parts have ~6 to 8 week leadtime.	

Attachment 2: – Stability Protocols – (see next 5 pages)

Siga Technologies**ST-246 214 mg/vial****Package Presentation: 30 mL vial****One Storage Orientation****One CTM batch (liquid product) will be placed on stability (one stability study)**

Study Attributes	Protocol Code
Physical Exam (Product Appearance of Liquid)	A
Active Potency (Complex HPLC Assay)	
Related Substances/Impurities (Same Complex HPLC Assay, no addn'l stds)	
Hydrazine (Complex HPLC Assay)	
pH	
SG1 Diacid	C
Particulate Matter (HIAC)	
Sterility	D
Bacterial Endotoxin (Gel Clot LAL)	

Study Activities and Use Fees

Thermal Chamber Use Fee (for 1 basket of samples per storage condition)	X
Sample labeling (for Sterile products)	
Stability framework, protocol, and database creation	Y
SLIM Database Reports	

Storage Conditions and Activities	Intervals in Months									
	0	1	3	6	9	12	18	24	36	48
Administrative	XY	Y	Y	Y	Y	Y	Y	Y	Y	Y
40C/75%RH	A,C,D ⁽¹⁾	A	A	A,C,D						
25C/60%RH		A	A	A,C	A	A,C,D	A	A,C	A	A
5C		A	A	A,C	A	A,C,D	A	A,C	A	A

⁽¹⁾ Assumed that Product Release Data will be used for the initial (T0) timepoint.

Price per Time point:	\$ 9,700	\$ 9,700	\$ 9,700	\$ 11,600	\$ 7,000	\$ 10,600	\$ 8,300	\$ 8,900	\$ 7,000	\$ 7,000	\$ 89,500
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Assumptions:

1) Analytical activities include the cost of reasonable and customary expendables associated with performing test methods, such as USP reference standards, solvents, and common HPLC columns, etc. However, some analyses may utilize especially numerous, particularly costly, or short-lived expendables, including limitedly available or expensive reference standards/markers as well as specialized, fragile, or short-lived HPLC columns, and other such "uncustomary" items. These limitedly available or atypically costly analytical items are not included in the analytical costs for this project and will either be provided by the client or billed to the client incrementally to the proposal price.

2) Assumed DSM has all required equipment and expertise to perform required tests (as listed in the bid).

3) Assumed that Product Release Data would be used for the initial (T0) timepoint.

4) The sample allocations provided by Siga are not sufficient to support these studies.

Siga Technologies
ST-246 214 mg/vial
Package Presentation: 30 mL vial - Liquid formulation
One Storage Orientation
One Placebo CTM batch placed on stability (one stability study)

Study Attributes	Protocol Code
Physical Exam (Product Appearance)	A
Active Potency (Complex HPLC Assay - Absence of Active)	A
Particulate Matter (HIAC)	C
Sterility	D
Bacterial Endotoxin (Gel Clot LAL)	D

Study Activities and Use Fees

Thermal Chamber Use Fee (for 1 basket of samples per storage condition)	X
Sample labeling (for Sterile products)	X
Stability framework, protocol, and database creation	X
SLIM Database Reports	Y

Storage Conditions and Activities	Intervals in Months								
	0	1	3	6	9	12	18	24	36
Administrative	XY	Y	Y	Y	Y	Y	Y	Y	Y
40C/75%RH	A,B,C,D,I ⁽¹⁾	A	A	A,C,D					
25C/60%RH		A	A	A,C	A	A,C,D	A	A	A
5C		A	A	A,C	A	A,C,D	A	A	A

⁽¹⁾ Assumed that Product Release Data will be used for the initial (T0)

Price per Time point: \$ 8,900 \$ 3,700 \$ 3,700 \$ 5,600 \$ 3,500 \$ 5,800 \$ 3,500 \$ 3,500 \$ 3,500

Assumptions:

- 1) Analytical activities include the cost of reasonable and customary expendables associated with performing test methods, such as USP reference standards, solvents, and common HPLC columns, etc. However, some analyses may utilize especially numerous, particularly costly, or short-lived expendables, including limitedly available or expensive reference standards/markers as well as specialized, fragile, or short-lived HPLC columns, and other such "uncustomary" items. These limitedly available or atypically costly analytical items are not included in the analytical costs for this project and will either be provided by the client or billed to the client incrementally to the proposal price.
- 2) Assumed DSM has all required equipment and expertise to perform required tests (as listed in the bid).
- 3) Assumed that Product Release Data would be used for the initial (T0) timepoint.
- 4) The sample allocations provided by Siga are not sufficient to support these studies.

Siga Technologies**ST-246 214 mg/vial****Package Presentation: 30 mL vial****One Storage Orientation****One Development batch (liquid product) will be placed on stability (one stability study)**

Study Attributes	Protocol Code
Physical Exam (Product Appearance of Liquid)	A
Active Potency (Complex HPLC Assay)	
Related Substances/Impurities (Same Complex HPLC Assay, no addn'l stds)	
Hydrazine (Complex HPLC Assay)	
pH	
SG1 Diacid (Outsourced)	C
Particulate Matter (HIAC)	

Study Activities and Use Fees

Thermal Chamber Use Fee (for 1 basket of samples per storage condition)	X
Sample labeling (for Sterile products)	
Stability framework, protocol, and database creation	Y
SLIM Database Reports	

Storage Conditions and Activities	Intervals in Months									
	0	1	3	6	9	12	18	24	36	48
Administrative	XY	Y	Y	Y	Y	Y	Y	Y	Y	Y
40C/75%RH	A,C ⁽¹⁾	A,C	A,C	A,C						
25C/60%RH		A	A	A	A	A,C	A	A,C	A	A
5C		A	A	A	A	A,C	A	A,C	A	A

⁽¹⁾ Assumed that Product Release Data will be used for the initial (T0) timepoint.

Price per Time point:	\$ 9,300	\$ 6,700	\$ 6,700	\$ 6,700	\$ 4,200	\$ 5,700	\$ 4,200	\$ 5,700	\$ 4,200	\$ 4,200	\$ 57,600
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Assumptions:

1) Analytical activities include the cost of reasonable and customary expendables associated with performing test methods, such as USP reference standards, solvents, and common HPLC columns, etc. However, some analyses may utilize especially numerous, particularly costly, or short-lived expendables, including limitedly available or expensive reference standards/markers as well as specialized, fragile, or short-lived HPLC columns, and other such "uncustomary" items. These limitedly available or atypically costly analytical items are not included in the analytical costs for this project and will either be provided by the client or billed to the client incrementally to the proposal price.

2) Assumed DSM has all required equipment and expertise to perform required tests (as listed in the bid).

3) Assumed that Product Release Data would be used for the initial (T0) timepoint.

4) The sample allocations provided by Siga are not sufficient to support these studies.

Siga Technologies**ST-246 214 mg/vial****Package Presentation: 50 mL vial (Lyo product)****One Storage Orientation****One Development batch placed on stability (one stability study)****Study Attributes****Protocol Code**

Physical Exam (Lyo Product Appearance)	A
Physical Exam (Reconstituted Product Appearance)	
Active Potency (Complex HPLC Assay)	
Related Substances/Impurities (Same Complex HPLC Assay, no addn'l stds)	
Hydrazine (Complex HPLC Assay)	
pH after reconstitution	
Dissolution/Reconstitution Time	
SG1 Diacid (Outsourced)	
Moisture Content (KF)	
Particulate Matter (HIAC)	C

Study Activities and Use Fees

Thermal Chamber Use Fee (for 1 basket of samples per storage condition)	X
Sample labeling (for Sterile products)	
Stability framework, protocol, and database creation	Y
SLIM Database Reports	

Storage Conditions and Activities	Intervals in Months									
	0	1	3	6	9	12	18	24	36	48
Administrative	XY	Y	Y	Y	Y	Y	Y	Y	Y	Y
40C/75%RH	A,C ⁽¹⁾	A	A	A,C						
25C/60%RH			A	A	A	A,C	A	A,C	A	A
5C ⁽²⁾			A	A	A	A,C	A	A,C	A	A
timepoint.										

Price per Time point: \$ 9,700 \$ 9,600 \$ 13,000 \$ 14,100 \$ 11,300 \$ 12,400 \$ 11,300 \$ 12,800 \$ 11,300 \$ 11,300 \$ 116,800

Assumptions:

- 1) Analytical activities include the cost of reasonable and customary expendables associated with performing test methods, such as USP reference standards, solvents, and common HPLC columns, etc. However, some analyses may utilize especially numerous, particularly costly, or short-lived expendables, including limitedly available or expensive reference standards/markers as well as specialized, fragile, or short-lived HPLC columns, and other such "uncustomary" items. These limitedly available or atypically costly analytical items are not included in the analytical costs for this project and will either be provided by the client or billed to the client incrementally to the proposal price.
- 2) Assumed DSM has all required equipment and expertise to perform required tests (as listed in the bid).
- 3) Assumed that Product Release Data would be used for the initial (T0) timepoint.
- 4) The sample allocations provided by Siga are not sufficient to support these studies.

Siga**ST-246 (10 mg/mL)****Photostability per ICH Option 2 on the IV Formulation (one stability study)**

Study Attributes	Protocol Code
Physical Exam (Product Appearance of Liquid)	A
Active Potency (Complex HPLC Assay)	
Related Substances/Impurities (Same Complex HPLC Assay, no addn'l stds)	
Hydrazine (Complex HPLC Assay)	
pH	
SG1 Diacid (Outsourced)	
Particulate Matter (HIAC)	

Study Activities and Use Fees

Thermal Chamber Use Fee (for 1 basket of samples per storage condition)	X
Sample labeling (for Sterile products)	
Stability framework, protocol, and database creation	
Light Chamber Use Fee	
SLIM Database Reports	Y

Storage Conditions and Activities	Intervals in Months		Total
	0	0.5	
Administrative	XY	Y	
ICH Option 2 Photostability Chamber (Unpackaged in Open Dish)		A ⁽¹⁾	
ICH Option 2 Photostability Chamber (Unpackaged in Open Dish - Dark Control)		A ⁽¹⁾	
ICH Option 2 Photostability Chamber (in Primary Packaging)		A ⁽¹⁾	
ICH Option 2 Photostability Chamber (in Primary Package - Dark Control)		A ⁽¹⁾	
⁽¹⁾ Treatment will likely not coincide with other testing for other storage stations			
⁽²⁾ Tested only if Open Dish UV/Fluorescent Chamber condition fails			

Price per Time point: \$ 7,200 \$ 19,300 \$ 26,500

Assumptions:

- 1) Photostability will be performed per ICH Option 2.
- 2) The open dish exposure and primary packaging samples will be exposed and tested simultaneously.
- 3) Assumed photostability would not coincide with any other testing.
- 4) Assumed that we would only perform photostability on the IV formulation (demo batch).
- 5) Assumed that we have enough samples to perform the photostability of the IV demo batch.

**Exhibit G to the
Services Agreement
Dated 12 January 2012**

Statement of Work #7

This Exhibit details the services that Company will provide to SIGA. The services under this Exhibit shall be conducted under and subject to the terms and conditions of the Services Agreement between SIGA and Company, hereinafter ("SA").

Scope of Services

The Scope of Services is applicable Raw Data Collection for Development Batch, Liquid Placebo and Liquid Active CTM Batch (see attachment A).

Payment Terms

Total charges for professional service fees and direct expenses will not exceed **\$9,000**. Upon the execution of this Exhibit, and unless the parties otherwise agree, Company shall invoice SIGA upon transmission of raw data, either electronically or by delivery of hard copies or CDs, to SIGA's Corvallis, OR location.

SIGA agrees to pay to Company according to the terms set forth in Paragraph 4 of the above-referenced SA.

Term of this Exhibit

Services will commence upon execution of this Exhibit and will be completed by December 31, 2012.

SIGA Technologies, Inc.

BY: Dennis E. Hruby DATE: 13 Sep 2012
NAME: Dennis E. Hruby, Ph.D.
TITLE: Chief Scientific Officer

DSM Pharmaceuticals, Inc.

BY: Laurence Thomas DATE: 30 Oct 2012
NAME: Laurence Thomas
TITLE: V.P. Marketing & Sales

Attachment A to Exhibit G to the SA dated 12 January 2012



DSM Pharmaceuticals, Inc.
5900 Martin Luther King Jr. Highway
Greenville, North Carolina 27834

August 24, 2012

Stephen Priebe, Ph.D.
4575 SW Research Way
Corvallis OR 97333

Re: Scope Change - Tecovirimat IV Raw Data Collection: Development Batch and CTM Batches

Dear Stephen:

Please find below the pricing for Tecovirimat IV raw data collection for the development batch and CTM batches.

Support Services

	Price
Raw Data Collection for Development Batch, Liquid Placebo and Liquid Active CTM Batch	\$ 9,000
Total:	\$9,000

The services under this Scope Change shall be conducted under and subject to the terms and conditions of the Services Agreement between SIGA and DSM dated January 12, 2012.

Please provide approval by signing below and send an executed copy and purchase order to my attention, via e-mail in PDF format.

Please feel free to contact me at 858.945.5332 should you have any questions.

SIGA Approval: Dennis E. Healy

Date: 13 Sep 2012

PO Number: 17027-090412

Kind Regards,

A handwritten signature in cursive script, appearing to read "Diane V. Lever".

Diane V. Lever
Sr. Account Director/Business Development

cc: Jennifer Adams
Shumena Horton
Kaye Byrd
Judy Moore

**Exhibit H to the
Services Agreement
Dated 12 January 2012**

Statement of Work #8

This Exhibit details the services that Company will provide to SIGA. The services under this Exhibit shall be conducted under and subject to the terms and conditions of the Services Agreement between SIGA and Company, hereinafter ("SA").

Scope of Services

The Scope of Services is applicable to Support Services as outlined in the Scope Change Document dated September 6, 2012 (see attachment A).

Payment Terms

Total charges for professional service fees and direct expenses will not exceed **\$4,000**. Company shall invoice SIGA on a yearly basis each September until such time that SIGA contacts company and requests, in writing, that sample retention is no longer necessary. This SOW shall expire at the conclusion of the Term stated below. Subsequent invoices for sample retention will be covered under Amendments to this SOW and corresponding Purchase Order. Upon the execution of this Exhibit, and unless the parties otherwise agree, Company shall invoice SIGA in full.

SIGA agrees to pay to Company according to the terms set forth in Paragraph 4 of the above-referenced SA.

Term of this Exhibit

Services will commence upon execution of this Exhibit and will be completed by August 31, 2013.

SIGA Technologies, Inc.

BY: Dennis E. Hruba
NAME: Dennis E. Hruba, Ph.D.
TITLE: Chief Scientific Officer

DATE: 14 Sep 2012

DSM Pharmaceuticals, Inc.

BY: Lawrence Thomas
NAME: Lawrence Thomas
TITLE: V.P. Marketing & Sales

DATE: 30 Oct 2012

Attachment A to Exhibit H to the SA dated 12 January 2012



DSM

BRIGHT SCIENCE. BRIGHTER LIVING.

DSM Pharmaceuticals, Inc.
5900 Martin Luther King Jr. Highway
Greenville, North Carolina 27834

September 6, 2012

Stephen Priebe, Ph.D.
4575 SW Research Way
Corvallis OR 97333

Re: Scope Change - Tecovirimat (ST-246 ®) Injection, Retain Sample Storage

Dear Stephen:

Please find below the pricing for Tecovirimat (ST-246 ®) Injection Retain Sample Storage

Support Services

	Price
Retain Sample Storage for CTM Active Batch (one storage bin per batch). Samples to be stored at room temperature.	\$2,000/year/batch
Retain Sample Storage for Placebo Batch (one storage bin per batch). Samples to be stored at room temperature.	\$2,000/year/batch

The services under this Scope Change shall be conducted under and subject to the terms and conditions of the Services Agreement between SIGA and DSM dated January 12, 2012.

Please provide approval by signing below and send an executed copy and purchase order to my attention, via e-mail in PDF format.

Please feel free to contact me at 858.945.5332 should you have any questions.

SIGA Approval: *Dennis E. Huley*

Date: 14 Sep 2012

PO Number: 17061-091212

Kind Regards,

Diane V. Lever

Diane V. Lever

Sr. Account Director/Business Development

cc: Jennifer Adams
Shumena Horton
Kaye Byrd
Judy Moore

**Exhibit I to the
Services Agreement
Dated 12 January 2012**

Statement of Work #9

This Exhibit details the services that Company will provide to SIGA. The services under this Exhibit shall be conducted under and subject to the terms and conditions of the Services Agreement between SIGA and Company, hereinafter ("SA").

Scope of Services

The Scope of Services is applicable to dilution stability studies of the ST-246 (tecovirimat) liquid IV drug product at the initial time point (0 hr). The IV liquid formulation is to be diluted with 2 parts of IV infusion solution for clinical dosing to achieve suitable volume, osmolality, and an acceptable concentration of hydroxypropyl betadex. Study details are presented in Attachment A (saline) and Attachment B (dextrose).

Payment Terms

Total charges for professional service fees and direct expenses will not exceed **\$78,300**. Upon the execution of this Exhibit, and unless the parties otherwise agree, Company shall invoice SIGA in full upon delivery of a draft stability summary reports for both IV dilution fluids.

SIGA agrees to pay to Company according to the terms set forth in Paragraph 4 of the above-referenced SA.

Term of this Exhibit

Services will commence upon execution of this Exhibit and will be completed by December 31, 2012.

SIGA Technologies, Inc.

BY:

NAME: Dennis E. Hruby, Ph.D.
TITLE: Chief Scientific Officer

DATE:

25 Oct 2012

DSM Pharmaceuticals, Inc.

BY:

NAME:
TITLE:

DATE:

1 Nov 2012

Attachment A

Siga
ST-246 Liquid Formulation
One Packaging Presentation
One Storage Orientation

Two Dilution Studies using Saline as the Diluent (for Initial):

1:2 Dilution using Saline as the Diluent

1:4 Dilution using Saline as the Diluent

Study Attributes	Protocol Code
Physical Exam (Product Appearance - includes color and visual particulates)	A
Particulate Matter (HIAC)	
Active Potency (Complex HPLC Assay)	B
Related Substances/Impurities (Same Cmplx HPLC Chromatogram, no addn'l stds)	
pH	C
Osmolality	
Preparation of Dilution Study Samples	D

Study Activities and Use Fees

Thermal Chamber Use Fee (for 1 basket of samples per storage condition)	X
Sample labeling (for Sterile products)	X
Stability framework, protocol, and database creation	X
SLIM Database Reports	Y

Storage Conditions and Activities	Intervals in Months		
	0 - 0 hr	0 - 24 hr	0-48 hr
Administrative	XY	Y	Y
Initial	A,B,C,D		
5C (Initial samples diluted with Saline 0 Hours)(1)			
5C (Initial samples diluted with Saline & stored at 5C for 24Hours)		A	
5C (Initial samples diluted with Saline & stored at 5C for 48Hours)			A,B
25C/60%RH (Initial samples diluted with Saline 0 Hours)(1)			
25C/60%RH (Initial samples diluted with Saline & stored at 25C/60%RH for 24Hours)		A	
25C/60%RH (Initial samples diluted with Saline & stored at 25C/60%RH for 48 Hours)			A,B
⁽¹⁾ Assumed that one zero hour testing event for which the results would be used for both the zero hour at 5C and 25C/60RH.			
⁽²⁾ Assumed that each set of samples (0 hrs, 24 hrs, and 48 hrs) must be tested immediately upon removal from the chamber (24 hr samples cannot be tested with the 48 hr samples).			

Price per Time point: \$ 30,600 | \$ 5,200 | \$ 16,400 | \$ 52,200

Assumptions:

- We will definitely have to stagger the storage of the studies in order to test the samples within the required amount of time.
- There will be four dilution studies for the liquid product.
 - A 1:2 dilution using Saline as the diluent
 - A 1:4 dilution using Saline as the diluent
- For the liquid studies, the plan is to store the two saline studies concurrently. Then a week to two weeks later, the two dextrose studies will be stored concurrently. However, we may have to store all four studies separately to ensure that we can complete the testing within the required timeframe. We will make this decision as we get closer to storing the samples.

Attachment B

Siga

ST-246 Liquid Formulation

One Packaging Presentation

One Storage Orientation

One Dilution Study using Dextrose as the Diluent (Initial):

1:2 Dilution using Dextrose as the Diluent

Note: The studies will not be stored/tested concurrently

Study Attributes	Protocol Code
Physical Exam (Product Appearance - includes color and visual particulates)	A
Particulate Matter (HIAC)	
Active Potency (Complex HPLC Assay)	B
Related Substances/Impurities (Same Cmplx HPLC Chromatogram, no addn'l stds)	
pH	C
Osmolality	
Preparation of Dilution Study Samples	D

Study Activities and Use Fees

Thermal Chamber Use Fee (for 1 basket of samples per storage condition)	X
Sample labeling (for Sterile products)	
Stability framework, protocol, and database creation	Y
SLIM Database Reports	

Storage Conditions and Activities	Intervals in Months		
	0 - 0 hr	0 - 24 hr	0-48 hr
Administrative	XY		
Initial			
5C (Initial samples diluted with Dextrose 0 Hours) ⁽¹⁾	A,B,C,D		
5C (Initial samples diluted with Dextrose & stored at 5C for 24Hours)		A	
5C (Initial samples diluted with Dextrose & stored at 5C for 48 Hours)			A,B
25C/60%RH (Initial samples diluted with Dextrose 0 Hours) ⁽¹⁾			
25C/60%RH (Initial samples diluted with Dextrose & stored at 25C/60%RH for 24Hours)		A	
25C/60%RH (Initial samples diluted with Dextrose & stored at 25C/60%RH for 48 Hours)			A,B
⁽¹⁾ Assumed that one zero hour testing event for which the results would be used for both the zero hour at 5C and 25C/60RH.			
⁽²⁾ Assumed that each set of samples (0 hrs, 24 hrs, and 48 hrs) must be tested immediately upon removal from the chamber (24 hr samples cannot be tested with the 48 hr samples).			

Price per Time point: \$ 15,300 \$ 2,600 \$ 8,200 \$ **26,100**

Assumptions:

- We will definitely have to stagger the storage of the studies in order to test the samples within the required amount of time.
- There will be four dilution studies for the liquid product.
A 1:2 dilution using Dextrose as the diluent
- For the liquid studies, the plan is to store the two saline studies concurrently. Then a week to two weeks later, the two dextrose studies will be stored concurrently. However, we may have to store all four studies separately to ensure that we can complete the testing within the required timeframe. We will make this decision as we get closer to storing the samples.

**Amendment 1 to Exhibit I to the
Services Agreement
Dated 12 January 2012**

Statement of Work #9

This Amendment 1 hereby modifies and is made an integral part of Statement of Work #9 ("SOW #9") between SIGA Technologies, Inc. ("SIGA") and DSM Pharmaceuticals, Inc. ("Company"), which was entered into pursuant to the Master Services Agreement between SIGA and Company dated January 12, 2012 ("SA").

Under and subject to the terms and conditions of the SA, SIGA and Company wish to amend and revise the scope of the services set forth in SOW #9 as set forth below.

SIGA and Company agree as follows:

Revised Scope of Services

The Scope of Services is applicable to dilution stability studies of the ST-246 (tecovirimat) liquid IV drug product at the initial time point (0 hr) and is revised as presented in Scope Change – Tecovirimat (ST-246[®]) Injection – Investigative Experiment dated 01 April 2013 attached hereto as Attachment A.

Fees and Payment Terms

Total charges for professional service fees and direct expenses for this Scope Change will not exceed \$2,500 bringing the total ceiling of Exhibit I to a not to exceed amount of **\$80,800**. Upon the full execution of this Amendment 1, and unless the parties otherwise agree, Company shall invoice SIGA on a monthly basis for work performed as it relates to the Revised Scope of Services. SIGA agrees to pay to Company according to the terms set forth in Paragraph 4 of the above-referenced SA.

Term

Services will commence upon full execution of this Amendment 1 and will be completed by July 31, 2013.

This Amendment 1 is issued pursuant to and, upon its full execution by SIGA and Company, shall become incorporated into SOW #9, which is incorporated into the SA.

The foregoing is the complete and final expression of the agreement between SIGA and Company to modify SOW #9 with respect to the Revised Scope of Services and cannot be modified, except by a writing signed by duly authorized representatives of both SIGA and Company.

By signing below, the authorized parties agree to the terms of this Amendment 1, effective as of the date of last signature below.

SIGA Technologies, Inc.

BY: Dennis E. Hruby DATE: 15 Apr 2013
NAME: Dennis E. Hruby, Ph.D.
TITLE: Chief Scientific Officer

DSM Pharmaceuticals, Inc.

BY: Lawrence Thomas DATE: 10 May 2013
NAME: Lawrence Thomas
TITLE: V.P. Marketing & Sales

Attachment A



DSM Pharmaceuticals, Inc.
5900 Martin Luther King Jr. Highway
Greenville, North Carolina 27834

April 1, 2013

Stephen Priebe, Ph.D.
4575 SW Research Way
Corvallis OR 97333

Re: Scope Change - Tecovirimat (ST-246 ®) Injection -Investigative Experiment

Dear Stephen:

Please find below the pricing for Tecovirimat (ST-246 ®) Injection investigative experiment. The scope change includes the protocol draft, execution, data composition, and data review per dilution (HIAC prep and run) x 3 proposed dilutions.

Support Services

	Price
Draft protocol. Execute tests for 3 dilutions (HIAC prep & run); and compose and review data.	\$ 2,500
Total	\$ 2,500

The services under this Scope Change shall be conducted under and subject to the terms and conditions of the Services Agreement between SIGA and DSM dated January 12, 2012.

Please provide approval by signing below and send an executed copy and purchase order to my attention, via e-mail in PDF format.

Please feel free to contact me at 858.945.5332 should you have any questions.

SIGA Approval: *Dennis E. Huley*

Date: 15 Apr 2013

PO Number: 17939-040813

Kind Regards,

Diane V. Lever
Diane V. Lever

Sr. Account Director/Business Development

cc: Jennifer Adams
Shumena Horton
Kaye Byrd
Judy Moore

**Exhibit J to the
Services Agreement
Dated 12 January 2012**

Statement of Work #10

This Exhibit details the services that Company will provide to SIGA. The services under this Exhibit shall be conducted under and subject to the terms and conditions of the Services Agreement between SIGA and Company, hereinafter ("SA").

Scope of Services

The Scope of Services is applicable to Tecovirimat (ST-246 ®) Injection Compatibility Study. Prepare ST-246 IV Formulation (about 150 mL) at 10 mg/mL in 40% (w/v) Kleptose in WFI. Into a 100 mL sterile vial or other suitable glass vessel, inject 20 mL of the ST-246 IV Formulation using a 30 mL BD syringe or pipet. Similarly, add 40 mL of 0.9% NaCl solution to the ST-246 IV Formulation in the vial/vessel. After mixing well, withdraw the 1+2 ST-246 IV Dilution into a 60 mL BD syringe. The filled BD syringe is then connected to a MS407 extension set and the tubing primed with the 1+2 ST-246 IV Dilution. Then dispense the 1+2 ST-246 IV Dilution slowly from the syringe and tubing into a suitable glass container. Perform the filling and dispensing in triplicate, in each case using a new syringe and MS407 extension set. Assay the collected solutions and determine related substances using the HPLC method described in DSM GVL 4093.

Deliverables include a draft and final protocol as well as a draft and final study report.

Payment Terms

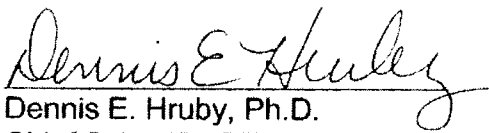
Total charges for professional service fees and direct expenses will not exceed **\$5,300** as outlined in Attachment A. Upon the execution of this Exhibit, and unless the parties otherwise agree, Company shall invoice SIGA in full upon delivery of a final compatibility study report.

SIGA agrees to pay to Company according to the terms set forth in Paragraph 4 of the above-referenced SA.

Term of this Exhibit

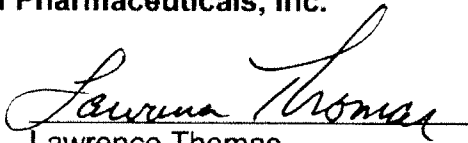
Services will commence upon execution of this Exhibit and will be completed by December 31, 2012.

SIGA Technologies, Inc.

BY: 
Dennis E. Hruby, Ph.D.
Chief Scientific Officer

DATE: 26 Nov 2012

DSM Pharmaceuticals, Inc.

BY: 
Lawrence Thomas
VP Marketing and Sales

DATE: 18 Dec 2012

Attachment A



DSM Pharmaceuticals, Inc.
5900 Martin Luther King Jr. Highway
Greenville, North Carolina 27834

November 15, 2012

Stephen Priebe, Ph.D.
4575 SW Research Way
Corvallis OR 97333

Re: Scope Change - Tecovirimat (ST-246 ®) Injection, Compatibility Study Design

Dear Stephen:

Please find below the pricing for Tecovirimat (ST-246 ®) Injection Compatibility Study Design.
The price includes a draft protocol/report and execution of the test.

Support Services

	Price
Compatibility Study Design: Draft protocol/report and execution of the test.	\$5,300

The services under this Scope Change shall be conducted under and subject to the terms and conditions of the Services Agreement between SIGA and DSM dated January 12, 2012.

Please provide approval by signing below and send an executed copy and purchase order to my attention, via e-mail in PDF format.

Please feel free to contact me at 858.945.5332 should you have any questions.

SIGA Approval: *Dennis E. Heuf* Date: 26 Nov 2012
PO Number: 17351-111612

Kind Regards,

A handwritten signature in cursive script, appearing to read "Diane V. Lever".

Diane V. Lever
Sr. Account Director/Business Development

cc: Jennifer Adams
Shumena Horton
Kaye Byrd
Judy Moore

**Exhibit K to the
Services Agreement
Dated 12 January 2012**

Statement of Work #11

This Exhibit details the services that Company will provide to SIGA. The services under this Exhibit shall be conducted under and subject to the terms and conditions of the Services Agreement between SIGA and Company, hereinafter ("SA").

Scope of Services

The Scope of Services is applicable to **one development batch of the tecovirimat (ST-246) IV drug product split into a lyophilized form and a liquid form on stability through the 48 month interval** as presented in **ST-246 Clinical Batch Proposal, Version 8**, dated **20 July 2012** (see attachment A).

Payment Terms

Total charges for professional service fees and direct expenses will not exceed **\$119,400**. Upon the execution of this Exhibit, and unless the parties otherwise agree, Company shall invoice SIGA in the following manner:

Stability through 48 months

Lyophilized product – \$14,100, \$11,300, \$12,400, \$11,300, \$12,800, \$11,300, \$11,300 – at each interval after the stability report is issued.

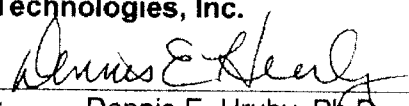
Liquid product – \$6,700, \$4,200, \$5,700, \$4,200, \$5,700, \$4,200, \$4,200 – at each interval after the stability report is issued.

SIGA agrees to pay to Company according to the terms set forth in Paragraph 4 of the above-referenced SA.

Term of this Exhibit

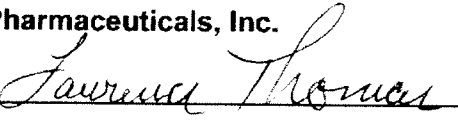
Services will commence upon execution of this Exhibit and will be completed by **February 18, 2018**.

SIGA Technologies, Inc.

BY: 
NAME: Dennis E. Hruba, Ph.D.
TITLE: Chief Scientific Officer

DATE: 04 Apr 2013

DSM Pharmaceuticals, Inc.

BY: 
NAME: Lawrence Thomas
TITLE:

DATE: 29 April 2013

Attachment A



ST-246 Clinical Batch Proposal

**Issued July 20, 2012
Version 8
for
SIGA Technologies, Inc.**

**Submitted By:
Diane Lever, Sr. Account Director/Business Development**

DSM Pharmaceuticals, Inc.
5900 Martin Luther King Jr. Highway
Greenville, NC 27834
www.dsmpharmaceuticalproducts.com

SIGA-ST-246

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- 1.1 Introduction
- 1.2 Proposal Summary
- 1.3 Terms of Supply

Section 2: Project Strategy

- 2.1 Standard Project Assumptions
- 2.2 Contacts Listing

Attachments

- Attachment 1: Capital
- Attachment 2: Stability

Section 1: Executive Summary

1.1 Introduction

DSM Pharmaceuticals Inc. (DPI) is a leading provider of product Development, Manufacturing and Packaging services to global Pharmaceutical & Biotechnology companies. Through continuous Investment and Innovation, and with a commitment to Quality and Security of Supply, DPI strives to be the preferred partner of choice for the production of sterile & solid dosage forms. Delivering outstanding service & value to our customers, combined with our experience, relevant expertise and state-of-the-art equipment, makes us uniquely qualified to support product success.

DPI Delivers **Total Value** to its Customers:

- A **Sustainable** Business Partner
 - 100 Year Legacy of Royal DSM N.V.
 - World Leader on the Dow Jones Sustainability Index
 - Solid, Independent Financial Position
- A **Compelling Facility**
 - 1.5MM square feet over 640 acres
 - All service offerings based at one site
 - DSM capital investment of \$176MM since 2001
- An **Unparalleled Level of Experience**
 - Continuous operations in Greenville, NC for 40 years
 - Development, Manufacturing & Packaging services
 - Average staff tenure of 14 years
 - Repeatedly launch 10 or more new products annually
- **Premium Quality** Systems & Processes
 - Fully-integrated, computerized systems such as SAP, Documentum and Trackwise
 - Proprietary, oracle-based software system called iMost, for planning, scheduling and as a data hub, offering complete visibility into production status
- Demonstrated **Regulatory Excellence**
 - Extraordinary international agency audit history
 - More than 90% of PAIs waived since 2007
- **DEA Licensed** Facility
 - Licensed to manufacture CII-CV products

DSM Pharmaceuticals, Inc. appreciates the opportunity to propose clinical trial material (CTM) pricing to **SIGA Technologies, Inc.** for **ST-246**, and looks forward to further discussions to ensure we fully address your team's specific needs. We are confident that DPI offers unique advantages, making us the best CMO option. DPI's leadership position in the CMO sector is driven by collaborative partnerships, with the goal of mutual success.

DSM Pharmaceuticals, Inc. wishes to thank SIGA Technologies, Inc. for their consideration of our experience, expertise and Commitment to Excellence.

1.2 Proposal Summary

This proposal is focused on providing pricing for early phase clinical liquid ST-246 product utilizing a 30cc qualified container closure system on DSM's CTM line for SIGA Technologies, Inc.

1.3 Terms of Supply

1.3.1 CTM Price

Batch Type	Batch Size Vials	Per Batch Price	Tiers
ST-246 (30mL vial) CTM	~1,800	\$80,000	1-2 CTM batches
ST-246 (30mL vial) CTM	~1,800	\$75,000	3-4 CTM batches
ST-246 (30mL vial) CTM	~1,800	\$70,000	> 4 CTM batches

- Price includes manufacturing, filling and bulk packaging into shippers.
- The following testing and QA release is included in price above:
Appearance, pH, Assay/Related Substances by HPLC, Hydrazine, Total Impurities, Particulate Matter, Osmolality, PFB, Sterility, and BET.
Assumes DSM will ship samples to Ricerca for contract testing of SG1Diacid.
- Price does not include the active ingredient or Kleptose, to be provided by SIGA Technologies, Inc.
- Assumes a 22mL fill volume.
- The container/closure to be used is a 30cc vial within DSM inventory. This vial and stopper is qualified on the CTM Line. DSM component item numbers: 30cc vial #321649, 20mm Stopper # 005305, Cap # 013329.
- Assumes product does not require nude vial labeling.
- Rescheduling fee of \$10,000 will be charged for changes within the 30-day firm zone. A CTM agreement that also contains quality terms will be required prior to manufacture of CTM batches.

CTM Transfer Services and Activities

Description	Pricing
Project Management Support Analytical Services -Develop and validate BET, Bioburden and Sterility methods -Analytical method transfers: <u>IV Formulation Product:</u> <ul style="list-style-type: none"> • Validate and transfer Assay and Related Substances (SG2, 4TFMBA, ST-246 Exo Isomer, Impurity A, SG1 hydrazide) by HPLC. • Trial alternative detection methods/techniques for SG1 Diacid • Validate and transfer Hydrazine • Verify Appearance of solution, pH, Particulate matter, Osmolality <u>Lyophilized Product (for development batch on stability):</u> Initial stability data for Assay/Related Substances and Hydrazine will be generated using analytical methods that will not be fully validated.	\$148,900
Validation Services -Validation CTM Line Assessment and Assessment Summary	\$8,000
Contract Lab testing to release Kleptose at DSM. Assumes 4 batches of Kleptose. Fee of \$8,400 per Kleptose batch.	\$33,600
Required set up activities for Kleptose. Full commercial set up is required since DSM will contract the testing. <ul style="list-style-type: none"> • Create an RMIR for material • Create an analytical standard for testing material • Create a sampling protocol • Create LIMS template 	\$12,400
Total:	\$202,900
ID test for final packaged CTM samples. (Optional)	\$2,400 per sample (Optional)

Batches:

Media Fills - not required due to change to DSM qualified 30cc liquid vial/stopper combination on the CTM line.	\$0
Lyo and Liquid Development Batch Manufacture (1) 50L batch split between Lyo and Liquid to support stability. Note: will not fill all of bulk into vials. - Assumes compounding in the CTM suite. Hand fill and lyophilize approximately 378 vials in the non-GMP area of Bldg 8 utilizing the 8 sq. ft. freeze dryer. - Assumes approximately a 50-60 hour lyo cycle. - For the Lyo portion - assumes a 50cc vial # 400015, 20mm stopper #005677 and Overseal # 013329. - Assumes ~600 vials to support the liquid formulation study. For the Liquid portion – assumes a 30cc vial	\$50,600
Liquid Placebo Batch (1) batch for Human Use (~1,800 vials). Must be completed in CTM Suite since a Human Use batch. Price includes set up of an analytical standard to support testing and stability.	See 1.3.1 of this proposal for batch pricing \$80,000
Liquid Active Batch (1) batch for Human Use (~1,800 vials) Must be completed in CTM Suite since for Human Use batch.	See 1.3.1 of this proposal for batch pricing \$80,000
Total:	\$210,600

Capital Estimate: \$26,840 See attachment #1 for additional information.

Stability Estimate: \$335,600

Study	Price
50cc Vial – One Lyo Development batch on stability	\$116,800
30cc Vial – One Liquid Development batch on stability	\$57,600
30cc Vial - One Liquid Active CTM batch on stability	\$89,500
30cc Vial - One Liquid Placebo CTM batch on stability	\$45,200
Photostability study	\$26,500

1. Testing based on ICH guidelines.
2. See Attachment #2 for stability protocols and time point pricing.

Section 2: Project Strategy

2.1 Project Scope

This project is intended to execute the clinical manufacturing transfer of ST-246 for SIGA to the CTM line in Steriles North. DSM will supply CTM product to SIGA. The strategy for executing this project is as follows:

SIGA's ST-246 is an aseptically filled liquid product in final dosage form. The product is intended for distribution in US clinical trials. The project requires at minimum the scope of work outlined in this proposal to qualify DSM as a site of manufacture for ST-246 CTM material.

The project's scope involves manufacturing, filling, and release of ST-246 CTM product and is therefore developmental in nature. As such, issues and unexpected outcomes are anticipated for which ongoing technical support by DSM may be required. Any unanticipated technical support is out of scope for this proposal.

In all aspects of this project, DSM is responsible for adhering to appropriate GMPs and sound defensible development or transfer plans which will be acceptable, in DSM's opinion, to current regulatory expectations.

2.2 CTM Strategy

2.2.1 Scope/ Contract Finalization

Following proposal approval, a CTM agreement that also contains quality terms will be approved by both organizations. After the CTM agreement is in place, the project will be initiated. Payment terms will be 14 days from invoice date.

2.2.2 Initial Process Feasibility/Transfer Activities

The CTM area Technical Representative will review the technical documents submitted by SIGA for the manufacture, filling and testing of ST-246. Documents to be prepared by DSM, with SIGA input and review should include formula and manufacturing instructions/batch record. SIGA will provide documents for API/BDS and product storage requirements.

Analytical services include:

- Set up Analytical standard for the API, Kleptose, IV Formulation and Lyo development Products
- Set up Analytical standard for the IV Formulation placebo batch
- Develop and Validate BET, Bioburden and Sterility Methods
- Assumes Appearance and ID on API.

Contract Lab testing to release Kleptose at DSM. Assumes 1 batch of Kleptose and fee applies to each batch if multiple batches are required.

Analytical method validation and transfers:

IV Formulation Product:

- Validate and transfer Assay and Related Substances (SG2, 4TFMBA, ST-246 Exo Isomer, Impurity A, SG1 hydrazide) by HPLC.
- Trial alternative detection methods/techniques for SG1 Diacid
- Validate and transfer Hydrazine
- Verify Appearance of solution, pH, Particulate matter and Osmolality.

The following testing and QA release is included in batch pricing: Appearance, Appearance of solution, pH, Assay/Related Substances by HPLC, Hydrazine, Total Impurities, Particulate Matter, Osmolality, PFB, Sterility, and BET.

Assumes DSM will ship samples to contract lab, Ricerca, for contract testing of SG1 Diacid.

2.2.3 CTM Services

CTM Batch – Multiple CTM batches are included in this proposal. All in process and finished product testing will be required.

One 30cc vial size - Liquid Development batch for stability only.
One 50cc vial size - Lyo Development batch for stability only.
One 30cc vial size - Liquid Placebo CTM batch
One 30cc vial size - Liquid Active CTM batch

2.2.4 Validation Services

Validation Services include a CTM Line Assessment and Assessment Summary.

Procedures for cleaning will be TOC for any equipment that is not disposable utilizing the DSM cleaning model. All filler product contact equipment is disposable.

2.2.5 Regulatory Services

DSM regulatory support activities are considered optional and are out of the scope of this proposal.

2.2.6 DSM Quality Assurance

DSM's Quality Assurance department will act as a compliance consultant and provide Quality oversight for adherence to regulatory requirements. This will include but not limited to the following: Documentation, Validation, and Investigations.

SIGA understands that DSM has considerable regulatory and compliance responsibility associated with this project. In all aspects of this project, DSM is responsible for adhering to appropriate GMPs and sound defensible development plans which will be acceptable, in DSM's opinion, to current regulatory expectations. DSM will not knowingly execute (or bypass) activities which are inconsistent with

the above or which will jeopardize DSM's regulatory status. At a minimum DSM's applicable Quality Systems must be met.

2.3 Standard Project Assumptions

2.3.1 General Assumptions

1. Project requires completion of a MSDS and assessment of Safety issues, potential environmental concerns, and waste disposal procedures, as appropriate, for this project. This proposal assumes the Chemical Health Protection rating is a CAT3 or less.
2. The API and excipients will be provided by the customer unless they are DSM current standard materials.
3. Customer will provide sufficient quantities of material for qualification of the BET and Sterility testing to be performed at DSM.
4. All materials supplied by SIGA Technologies, Inc. will arrive at DSM with appropriate documentation to be received into DSM's inventory, a certificate of analysis, certificate of compliance and chain of custody.
5. Standard DSM Documentation will be used for the filling process using the customer's critical parameters and process.
6. Storage condition of API and finished product will be controlled room temperature with ambient humidity.
7. A double sterile filtration will be performed.
8. Fill weight checks are part of the standard DSM process.
9. Inspection of the vials will include inspection for container closure and foreign matter (no product or cosmetic inspection). No retain samples will be taken or held at DSM.
10. Batch records review will be performed by DSM before QA release of the CTM batch. However upon request, product may be shipped under conditional status.
11. All unused material supplied by the customer will be returned or destroyed within 90 days of production if no additional demand is required.
12. Shipping of product, product samples, and documentation will be freight collect FOB Greenville. DSM will tender the materials to an approved carrier.

2.3.2 Optional Services Upon Request

- Regulatory Affairs documentation support.

2.3.3 Excluded materials or activities

Controlled or Cytotoxic substances are excluded materials from this production area.

1. DSM does not provide CTM labeling or final packaging at this time.
2. Phase III services are available and manufactured on commercial equipment.
3. Temperature controlled processing is not available on this equipment. Temperature controlled storage of API and finished product is available for specific temperature ranges.

2.4 Contacts Listing

Primary DSM contacts for this proposal are as follows:

Table 1: Contacts

Name	Phone number	Role	E-mail address
Diane Lever	510-524-2852	Sr. Account Director/Business Development	Diane.Lever@DSM.com
Ray Braxton	252-707-7240	CTM Manager-Technical Lead	Ray.braxton@DSM.com
Jennifer Adams	252-707-2049	Business Services	Jennifer.Adams@DSM.com

Attachment 1: Capital Estimate

Siga Technologies, Inc. (ST-246) Capital Estimate for CTM Line - North	
DESCRIPTION	BUDGET
50 ml vial size 20mm stopper, 25 ml fill - Lyo product	AMOUNT
EQUIPMENT	
Washer change parts (50 ml vial)	8,000
Misc. Tubing & Fittings and instruments	5,000
Filler change parts (50 ml vial)	8,000
FREIGHT	700
TAXES	700
ENGINEERING	2,000
Subtotal	24,400
CONTINGENCY @ 10%	2,440
Total	\$26,840
Change parts have ~6 to 8 week leadtime.	

Attachment 2: – Stability Protocols – (see next 5 pages)

Siga Technologies**ST-246 214 mg/vial****Package Presentation: 30 mL vial****One Storage Orientation****One CTM batch (liquid product) will be placed on stability (one stability study)**

Study Attributes	Protocol Code
Physical Exam (Product Appearance of Liquid)	A
Active Potency (Complex HPLC Assay)	
Related Substances/Impurities (Same Complex HPLC Assay, no addn'l stds)	
Hydrazine (Complex HPLC Assay)	
pH	
SG1 Diacid	C
Particulate Matter (HIAC)	
Sterility	D
Bacterial Endotoxin (Gel Clot LAL)	

Study Activities and Use Fees

Thermal Chamber Use Fee (for 1 basket of samples per storage condition)	X
Sample labeling (for Sterile products)	
Stability framework, protocol, and database creation	Y
SLIM Database Reports	

Storage Conditions and Activities	Intervals in Months									
	0	1	3	6	9	12	18	24	36	48
Administrative	XY	Y	Y	Y	Y	Y	Y	Y	Y	Y
40C/75%RH	A,C,D ⁽¹⁾	A	A	A,C,D						
25C/60%RH		A	A	A,C	A	A,C,D	A	A,C	A	A
5C		A	A	A,C	A	A,C,D	A	A,C	A	A

⁽¹⁾ Assumed that Product Release Data will be used for the initial (T0) timepoint.

Price per Time point:	\$ 9,700	\$ 9,700	\$ 9,700	\$ 11,600	\$ 7,000	\$ 10,600	\$ 8,300	\$ 8,900	\$ 7,000	\$ 7,000	\$ 89,500
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Assumptions:

1) Analytical activities include the cost of reasonable and customary expendables associated with performing test methods, such as USP reference standards, solvents, and common HPLC columns, etc. However, some analyses may utilize especially numerous, particularly costly, or short-lived expendables, including limitedly available or expensive reference standards/markers as well as specialized, fragile, or short-lived HPLC columns, and other such "uncustomary" items. These limitedly available or atypically costly analytical items are not included in the analytical costs for this project and will either be provided by the client or billed to the client incrementally to the proposal price.

2) Assumed DSM has all required equipment and expertise to perform required tests (as listed in the bid).

3) Assumed that Product Release Data would be used for the initial (T0) timepoint.

4) The sample allocations provided by Siga are not sufficient to support these studies.

Siga Technologies
ST-246 214 mg/vial
Package Presentation: 30 mL vial - Liquid formulation
One Storage Orientation
One Placebo CTM batch placed on stability (one stability study)

Study Attributes	Protocol Code
Physical Exam (Product Appearance)	A
Active Potency (Complex HPLC Assay - Absence of Active)	A
Particulate Matter (HIAC)	C
Sterility	D
Bacterial Endotoxin (Gel Clot LAL)	D

Study Activities and Use Fees

Thermal Chamber Use Fee (for 1 basket of samples per storage condition)	X
Sample labeling (for Sterile products)	X
Stability framework, protocol, and database creation	X
SLIM Database Reports	Y

Storage Conditions and Activities	Intervals in Months								
	0	1	3	6	9	12	18	24	36
Administrative	XY	Y	Y	Y	Y	Y	Y	Y	Y
40C/75%RH	A,B,C,D,I ⁽¹⁾	A	A	A,C,D					
25C/60%RH		A	A	A,C	A	A,C,D	A	A	A
5C		A	A	A,C	A	A,C,D	A	A	A

⁽¹⁾ Assumed that Product Release Data will be used for the initial (T0)

Price per Time point: \$ 8,900 \$ 3,700 \$ 3,700 \$ 5,600 \$ 3,500 \$ 5,800 \$ 3,500 \$ 3,500 \$ 3,500

Assumptions:

- 1) Analytical activities include the cost of reasonable and customary expendables associated with performing test methods, such as USP reference standards, solvents, and common HPLC columns, etc. However, some analyses may utilize especially numerous, particularly costly, or short-lived expendables, including limitedly available or expensive reference standards/markers as well as specialized, fragile, or short-lived HPLC columns, and other such "uncustomary" items. These limitedly available or atypically costly analytical items are not included in the analytical costs for this project and will either be provided by the client or billed to the client incrementally to the proposal price.
- 2) Assumed DSM has all required equipment and expertise to perform required tests (as listed in the bid).
- 3) Assumed that Product Release Data would be used for the initial (T0) timepoint.
- 4) The sample allocations provided by Siga are not sufficient to support these studies.

Siga Technologies**ST-246 214 mg/vial****Package Presentation: 30 mL vial****One Storage Orientation****One Development batch (liquid product) will be placed on stability (one stability study)**

Study Attributes	Protocol Code
Physical Exam (Product Appearance of Liquid)	A
Active Potency (Complex HPLC Assay)	
Related Substances/Impurities (Same Complex HPLC Assay, no addn'l stds)	
Hydrazine (Complex HPLC Assay)	
pH	
SG1 Diacid (Outsourced)	C
Particulate Matter (HIAC)	

Study Activities and Use Fees

Thermal Chamber Use Fee (for 1 basket of samples per storage condition)	X
Sample labeling (for Sterile products)	
Stability framework, protocol, and database creation	Y
SLIM Database Reports	

Storage Conditions and Activities	Intervals in Months									
	0	1	3	6	9	12	18	24	36	48
Administrative	XY	Y	Y	Y	Y	Y	Y	Y	Y	Y
40C/75%RH	A,C ⁽¹⁾	A,C	A,C	A,C						
25C/60%RH		A	A	A	A	A,C	A	A,C	A	A
5C		A	A	A	A	A,C	A	A,C	A	A

⁽¹⁾ Assumed that Product Release Data will be used for the initial (T0) timepoint.

Price per Time point:	\$ 9,300	\$ 6,700	\$ 6,700	\$ 6,700	\$ 4,200	\$ 5,700	\$ 4,200	\$ 5,700	\$ 4,200	\$ 4,200	\$ 57,600
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Assumptions:

1) Analytical activities include the cost of reasonable and customary expendables associated with performing test methods, such as USP reference standards, solvents, and common HPLC columns, etc. However, some analyses may utilize especially numerous, particularly costly, or short-lived expendables, including limitedly available or expensive reference standards/markers as well as specialized, fragile, or short-lived HPLC columns, and other such "uncustomary" items. These limitedly available or atypically costly analytical items are not included in the analytical costs for this project and will either be provided by the client or billed to the client incrementally to the proposal price.

2) Assumed DSM has all required equipment and expertise to perform required tests (as listed in the bid).

3) Assumed that Product Release Data would be used for the initial (T0) timepoint.

4) The sample allocations provided by Siga are not sufficient to support these studies.

Siga Technologies**ST-246 214 mg/vial****Package Presentation: 50 mL vial (Lyo product)****One Storage Orientation****One Development batch placed on stability (one stability study)****Study Attributes****Protocol Code**

Physical Exam (Lyo Product Appearance)	A
Physical Exam (Reconstituted Product Appearance)	
Active Potency (Complex HPLC Assay)	
Related Substances/Impurities (Same Complex HPLC Assay, no addn'l stds)	
Hydrazine (Complex HPLC Assay)	
pH after reconstitution	
Dissolution/Reconstitution Time	
SG1 Diacid (Outsourced)	
Moisture Content (KF)	
Particulate Matter (HIAC)	C

Study Activities and Use Fees

Thermal Chamber Use Fee (for 1 basket of samples per storage condition)	X
Sample labeling (for Sterile products)	
Stability framework, protocol, and database creation	Y
SLIM Database Reports	

Storage Conditions and Activities	Intervals in Months									
	0	1	3	6	9	12	18	24	36	48
Administrative	XY	Y	Y	Y	Y	Y	Y	Y	Y	Y
40C/75%RH	A,C ⁽¹⁾	A	A	A,C						
25C/60%RH			A	A	A	A,C	A	A,C	A	A
5C ⁽²⁾			A	A	A	A,C	A	A,C	A	A
timepoint.										

Price per Time point: \$ 9,700 \$ 9,600 \$ 13,000 \$ 14,100 \$ 11,300 \$ 12,400 \$ 11,300 \$ 12,800 \$ 11,300 \$ 11,300 \$ 116,800

Assumptions:

- 1) Analytical activities include the cost of reasonable and customary expendables associated with performing test methods, such as USP reference standards, solvents, and common HPLC columns, etc. However, some analyses may utilize especially numerous, particularly costly, or short-lived expendables, including limitedly available or expensive reference standards/markers as well as specialized, fragile, or short-lived HPLC columns, and other such "uncustomary" items. These limitedly available or atypically costly analytical items are not included in the analytical costs for this project and will either be provided by the client or billed to the client incrementally to the proposal price.
- 2) Assumed DSM has all required equipment and expertise to perform required tests (as listed in the bid).
- 3) Assumed that Product Release Data would be used for the initial (T0) timepoint.
- 4) The sample allocations provided by Siga are not sufficient to support these studies.

Siga

ST-246 (10 mg/mL)

Photostability per ICH Option 2 on the IV Formulation (one stability study)

Study Attributes	Protocol Code
Physical Exam (Product Appearance of Liquid)	A
Active Potency (Complex HPLC Assay)	
Related Substances/Impurities (Same Complex HPLC Assay, no addn'l stds)	
Hydrazine (Complex HPLC Assay)	
pH	
SG1 Diacid (Outsourced)	
Particulate Matter (HIAC)	

Study Activities and Use Fees

Thermal Chamber Use Fee (for 1 basket of samples per storage condition)	X
Sample labeling (for Sterile products)	
Stability framework, protocol, and database creation	
Light Chamber Use Fee	
SLIM Database Reports	Y

Storage Conditions and Activities	Intervals in Months		Total
	0	0.5	
Administrative	XY	Y	
ICH Option 2 Photostability Chamber (Unpackaged in Open Dish)		A ⁽¹⁾	
ICH Option 2 Photostability Chamber (Unpackaged in Open Dish - Dark Control)		A ⁽¹⁾	
ICH Option 2 Photostability Chamber (in Primary Packaging)		A ⁽¹⁾	
ICH Option 2 Photostability Chamber (in Primary Package - Dark Control)		A ⁽¹⁾	
⁽¹⁾ Treatment will likely not coincide with other testing for other storage stations			
⁽²⁾ Tested only if Open Dish UV/Fluorescent Chamber condition fails			

Price per Time point: \$ 7,200 \$ 19,300 \$ 26,500

Assumptions:

- 1) Photostability will be performed per ICH Option 2.
- 2) The open dish exposure and primary packaging samples will be exposed and tested simultaneously.
- 3) Assumed photostability would not coincide with any other testing.
- 4) Assumed that we would only perform photostability on the IV formulation (demo batch).
- 5) Assumed that we have enough samples to perform the photostability of the IV demo batch.

**Exhibit L to the
Services Agreement
Dated 12 January 2012**

Statement of Work #12

This Exhibit details the services that Company will provide to SIGA. The services under this Exhibit shall be conducted under and subject to the terms and conditions of the Services Agreement between SIGA and Company, hereinafter ("SA").

Scope of Services

The Scope of Services is applicable to **stability evaluation of one (1) liquid placebo batch of ST-246 CTM for human use and one (1) liquid active batch of ST-246 CTM for human use** beginning at the **3 month** and continuing through the **60 month interval** as presented in **ST-246 Clinical Batch Proposal, Version 8, Rev 05 September 2012** (see attachment A).

Payment Terms

Total charges for professional service fees and direct expenses will not exceed **\$95,700**. Upon the execution of this Exhibit, and unless the parties otherwise agree, Company shall invoice SIGA in the following manner:

Stability through 60 months: Placebo (\$1,300, \$1,900, \$1,100, \$2,800, \$1,100, \$2,800, \$1,500, \$1,500, \$1,500) – at each interval after the stability report is issued.

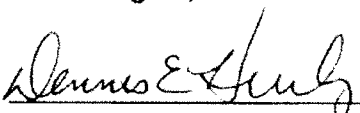
Stability through 60 months: Active (\$9,700, \$9,700, \$8,300, \$8,900, \$8,300, \$8,900, \$8,800, \$8,800, \$8,800) – at each interval after the stability report is issued.

SIGA agrees to pay to Company according to the terms set forth in Paragraph 4 of the above-referenced SA.

Term of this Exhibit

Services will commence upon execution of this Exhibit and will be completed by **February 18, 2018**.

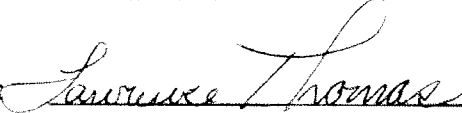
SIGA Technologies, Inc.

By: 

Name: Dennis E. Hruby, Ph.D.
Title: Chief Scientific Officer

Date: 28 Mar 2013

DSM Pharmaceuticals

By: 

Name: Lawrence Thomas
Title: V.P. Marketing & Sales

Date: 8 April 2013

Attachment A

Siga Technologies**ST-246 214 mg/vial****Package Presentation: 30 mL vial****One Storage Orientation****One CTM batch (liquid product) will be placed on stability (one stability study)**

Study Attributes	Protocol Code
Physical Exam (Product Appearance of Liquid)	A
Active Potency (Complex HPLC Assay)	
Related Substances/Impurities (Same Complex HPLC Assay, no addn'l stds)	
Hydrazine (Complex HPLC Assay)	
pH	
SG1 Diacid	
Particulate Matter (HIAC)	C
Sterility	
Bacterial Endotoxin (Gel Clot LAL)	D

Study Activities and Use Fees

Thermal Chamber Use Fee (for 1 basket of samples per storage condition)	X
Sample labeling (for Sterile products)	
Stability framework, protocol, and database creation	Y
SLIM Database Reports	

Storage Conditions and Activities	Intervals in Months											Total
	0	1	3	6	9	12	18	24	36	48	60	
Administrative	XY	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	
40C/75%RH	A,C,D ⁽¹⁾	A	A	A								
25C/60%RH		A	A	A	A	A,C	A	A,C	A	A	A	
5C		A	A	A	A	A,C	A	A,C	A,C	A,C	A,C	

⁽¹⁾ Assumed that Product Release Data will be used for the initial (T0) timepoint.

Price per Time point:	\$ 10,800	\$ 9,700	\$ 9,700	\$ 9,700	\$ 8,300	\$ 8,900	\$ 8,300	\$ 8,900	\$ 8,800	\$ 8,800	\$ 8,800	\$ 100,700
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Assumptions:

- 1) Analytical activities include the cost of reasonable and customary expendables associated with performing test methods, such as USP reference standards, solvents, and
- 2) Assumed DSM has all required equipment and expertise to perform required tests (as listed in the bid).
- 3) Assumed that Product Release Data would be used for the initial (T0) timepoint.
- 4) The sample allocations provided by Siga are not sufficient to support these studies.

Siga Technologies

ST-246 214 mg/vial

Package Presentation: 30 mL vial - Liquid formulation

One Storage Orientation

One Placebo CTM batch placed on stability (one stability study)

Study Attributes	Protocol Code
Physical Exam (Product Appearance)	A
pH	A
Particulate Matter (HIAC)	B
Sterility	C
Bacterial Endotoxin (Gel Clot LAL)	D

Study Activities and Use Fees

Thermal Chamber Use Fee (for 1 basket of samples per storage condition)	X
Sample labeling (for Sterile products)	X
Stability framework, protocol, and database creation	X
SLIM Database Reports	Y

Storage Conditions and Activities	Intervals in Months											Total
	0	1	3	6	9	12	18	24	36	48	60	
	XY	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	
	A,B,C,D,I ⁽¹⁾	A, B	A	A, B								
		A, B	A	A, B	A	A,B,C	A	A,B,C	A	A	A	
5C		A, B	A	A, B	A	A,B,C	A	A,B,C	A, B	A, B	A, B	
timepoint.												
Price per Time point: \$ 9,900 \$ 1,900 \$ 1,300 \$ 1,900 \$ 1,100 \$ 2,800 \$ 1,100 \$ 2,800 \$ 1,500 \$ 1,500 \$ 1,500 \$ 27,300												

Assumptions:

- 1) Analytical activities include the cost of reasonable and customary expendables associated with performing test methods, such as USP reference standards, solvents, and common HPLC columns, etc. However, some analyses may utilize especially numerous, par
- 2) Assumed DSM has all required equipment and expertise to perform required tests (as listed in the bid).
- 3) Assumed that Product Release Data would be used for the initial (T0) timepoint.
- 4) The sample allocations provided by Siga are not sufficient to support these studies.

**Exhibit M to the
Services Agreement
Dated 12 January 2012**

Statement of Work #13

This Exhibit details the services that Company will provide to SIGA. The services under this Exhibit shall be conducted under and subject to the terms and conditions of the Services Agreement between SIGA and Company, hereinafter ("SA").

Scope of Services

The Scope of Services is applicable Raw Data Collection for Development Batch, Liquid Placebo and Liquid Active CTM Batch (see attachment A).

Payment Terms

Total charges for professional service fees and direct expenses will not exceed **\$42,000**. Upon the execution of this Exhibit, and unless the parties otherwise agree, Company shall invoice SIGA **\$9,000 per year** upon transmission of raw data, either electronically or by delivery of hard copies or CDs, to SIGA's Corvallis, OR location beginning in year 2013 through 2016, inclusive. Company shall invoice SIGA **\$6,000 in 2017** upon transmission of raw data, either electronically or by delivery of hard copies or CDs, to SIGA's Corvallis, OR location. The reason for the difference in cost for 2017 is due to discontinuation of the development batch stability after 48 months (2016).

SIGA agrees to pay to Company according to the terms set forth in Paragraph 4 of the above-referenced SA.

Term of this Exhibit

Services will commence upon execution of this Exhibit and will be completed by February 18, 2018.

SIGA Technologies, Inc.

By: Dennis E. Hruby

Name: Dennis E. Hruby, Ph.D.

Title: Chief Scientific Officer

Date: 28 Mar 2013

DSM Pharmaceuticals

By: Lawrence Thomas

Name: Lawrence Thomas

Title: V.P. Marketing & Sales

Date: 8 April 2013

Attachment A



DSM Pharmaceuticals, Inc.
5900 Martin Luther King Jr. Highway
Greenville, North Carolina 27834

August 24, 2012

Stephen Priebe, Ph.D.
4575 SW Research Way
Corvallis OR 97333

Re: Scope Change - Tecovirimat IV Raw Data Collection: Development Batch and CTM Batches

Dear Stephen:

Please find below the pricing for Tecovirimat IV raw data collection for the development batch and CTM batches.

Support Services

	Price
Raw Data Collection for Development Batch, Liquid Placebo and Liquid Active CTM Batch	\$ 9,000
Total:	\$9,000

The services under this Scope Change shall be conducted under and subject to the terms and conditions of the Services Agreement between SIGA and DSM dated January 12, 2012.

Please provide approval by signing below and send an executed copy and purchase order to my attention, via e-mail in PDF format.

Please feel free to contact me at 858.945.5332 should you have any questions.

SIGA Approval: *Dennis E. Adams* Date: 20 Mar 2013

PO Number: 17902-032713

Kind Regards,

Dennis E. Adams
Dennis E. Adams

Sr. Account Director/Business Development

cc: Jennifer Adams
Shumena Horton
Kaye Byrd
Judy Moore

**Exhibit N to the
Services Agreement
Dated 12 January 2012**

Statement of Work #14

This Exhibit details the services that Company will provide to SIGA. The services under this Exhibit shall be conducted under and subject to the terms and conditions of the Services Agreement between SIGA and Company, hereinafter ("SA").

Scope of Services

The Scope of Services is applicable to dilution stability studies of the ST-246 (tecovirimat) liquid IV drug product at the 12 and 24 month time points. The IV liquid formulation is to be diluted for clinical dosing to achieve suitable volume, osmolality, and an acceptable concentration of hydroxypropyl betadex. Study details are presented in Attachment A.

Payment Terms

Total charges for professional service fees and direct expenses will not exceed **\$121,600**. Upon the execution of this Exhibit, and unless the parties otherwise agree, Company shall invoice SIGA for the **initial \$60,800** upon delivery of final stability summary reports for the **12 month interval** and the **remaining \$60,800** upon delivery of final stability summary reports for the **24 month interval**.

SIGA agrees to pay to Company according to the terms set forth in Paragraph 4 of the above-referenced SA.

Term of this Exhibit

Services will commence upon execution of this Exhibit and will be completed by March, 31, 2015.

SIGA Technologies, Inc.

By: Dennis E. Hruby

Name: Dennis E. Hruby, Ph.D.

Title: Chief Scientific Officer

Date: 16 Sept 2013

DSM Pharmaceuticals

By: Laurence Thomas

Name: Laurence Thomas

Title: V.P. Mfg

Date: 18 Sept. 2013

Attachment A

Siga
ST-246 Liquid Formulation
One Packaging Presentation
One Storage Orientation

Two Dilution Studies using Saline as the Diluent (12 month and 24 month):

1:2 Dilution using Saline as the Diluent

1:4 Dilution using Saline as the Diluent

Study Attributes	Protocol Code
Physical Exam (Product Appearance - includes color and visual particulates)	A
Particulate Matter (HIAC)	
Active Potency (Complex HPLC Assay)	B
Related Substances/Impurities (Same Cmplx HPLC Chromatogram, no addn'l stds)	
pH	
Osmolality	C
Preparation of Dilution Study Samples	D

Study Activities and Use Fees

Thermal Chamber Use Fee (for 1 basket of samples per storage condition)	X
Sample labeling (for Sterile products)	
Stability framework, protocol, and database creation	Y
SLIM Database Reports	

Storage Conditions and Activities	Intervals in Months					
	12 - 0 hr	12 - 24 hr	12-48 hr	24 - 0 hr	24 - 24 hr	24 - 48 hr
Administrative	Y	Y	Y	Y	Y	Y
25C/60%RH						
5C (25C/60%RH samples diluted with Saline 0 Hours)(1)	A,B,D			A,B,D		
5C (25C/60%RH samples diluted with Saline & stored at 5C for 24Hours)		A			A	
5C (25C/60%RH samples diluted with Saline & stored at 5C for 48 Hours)			A,B			A,B
25C/60%RH (25C/60%RH samples diluted with Saline 0 Hours)(1)						
25C/60%RH (25C/60%RH samples diluted with Saline & stored at 25C/60%RH for 24Hours)		A			A	
25C/60%RH (25C/60%RH samples diluted with Saline & stored at 25C/60%RH for 48 Hours)			A,B			A,B
5C	A,B,D			A,B,D		
5C (5C samples diluted with Saline 0 Hours)(1)						
5C (5C samples diluted with Saline & stored at 5C for 24Hours)		A			A	
5C (5C samples diluted with Saline & stored at 5C for 48 Hours)			A,B			A,B
25C/60%RH (5C samples diluted with Saline 0 Hours)(1)						
25C/60%RH (5C samples diluted with Saline & stored at 25C/60%RH for 24Hours)		A			A	
25C/60%RH (5C samples diluted with Saline & stored at 25C/60%RH for 48 Hours)			A,B			A,B

⁽¹⁾ Assumed that one zero hour testing event for which the results would be used for both the zero hour at 5C and 25C/60RH.

Price per Time point:	\$ 30,800	\$ 7,400	\$ 22,600	\$ 30,800	\$ 7,400	\$ 22,600	\$ 121,600
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Assumptions:

- We will definitely have to stagger the storage of the studies in order to test the samples within the required amount of time.
- There will be four dilution studies for the liquid product.
 - A 1:2 dilution using Saline as the diluent
 - A 1:4 dilution using Saline as the diluent
- For the liquid studies, the plan is to store the two saline studies concurrently. Then a week to two weeks later, the two dextrose studies will be stored concurrently. However, we may have to store all four studies separately to ensure that we can complete the testing within the required timeframe. We will make this decision as we get closer to storing the samples.

**Exhibit O to the
Services Agreement
Dated 12 January 2012**

Statement of Work #15

This Exhibit details the services that Company will provide to SIGA. The services under this Exhibit shall be conducted under and subject to the terms and conditions of the Services Agreement between SIGA and Company, hereinafter ("SA").

Scope of Services

The Scope of Services is applicable to Support Services as outlined in the Scope Change Document dated September 6, 2012 (see attachment A).

Payment Terms

Total charges for professional service fees and direct expenses will not exceed **\$20,000**. Company shall invoice SIGA **\$4,000 on a yearly basis** each September until such time that SIGA contacts company and requests, in writing, that sample retention is no longer necessary.

SIGA agrees to pay to Company according to the terms set forth in Paragraph 4 of the above-referenced SA.

Term of this Exhibit

Services will commence upon execution of this Exhibit and will be completed by February 18, 2018.

SIGA Technologies, Inc.

BY: Dennis E. Hruby
NAME: Dennis E. Hruby, Ph.D.
TITLE: Chief Scientific Officer

DATE: 29 Jul 2013

DSM Pharmaceuticals, Inc.

BY: Laurie Thomas
NAME:
TITLE:

DATE: 19 Aug 2013

Attachment A



DSM Pharmaceuticals, Inc.
5900 Martin Luther King Jr. Highway
Greenville, North Carolina 27834

September 6, 2012

Stephen Priebe, Ph.D.
4575 SW Research Way
Corvallis OR 97333

Re: Scope Change - Tecovirimat (ST-246 ®) Injection, Retain Sample Storage

Dear Stephen:

Please find below the pricing for Tecovirimat (ST-246 ®) Injection Retain Sample Storage

Support Services

	Price
Retain Sample Storage for CTM Active Batch (one storage bin per batch). Samples to be stored at room temperature.	\$2,000/year/batch
Retain Sample Storage for Placebo Batch (one storage bin per batch). Samples to be stored at room temperature.	\$2,000/year/batch

The services under this Scope Change shall be conducted under and subject to the terms and conditions of the Services Agreement between SIGA and DSM dated January 12, 2012.

Please provide approval by signing below and send an executed copy and purchase order to my attention, via e-mail in PDF format.

Please feel free to contact me at 858.945.5332 should you have any questions.

SIGA Approval:

Dennis E. Huley

Date:

29 Jul 2013

PO Number:

18388-072213

Kind Regards,

Dennis E. Huley
Dennis E. Huley

Sr. Account Director/Business Development

cc: Jennifer Adams
Shumena Horton
Kaye Byrd
Judy Moore

**Exhibit P to the
Services Agreement
Dated 12 January 2012**

Statement of Work #16

This Exhibit details the services that Company will provide to SIGA. The services under this Exhibit shall be conducted under and subject to the terms and conditions of the Services Agreement between SIGA and Company, hereinafter ("SA").

Scope of Services

The Scope of Services is applicable to Support Services as outlined in the **Scope Change – Tecovirimat (ST-246®) Injection - Storage Fees Revised Document** dated 11 April 2013 attached hereto as Attachment A.

Payment Terms

Total charges for professional service fees and direct expenses will not exceed **\$24,000**. Company shall invoice SIGA **\$4,800 on a yearly basis** each May until such time that SIGA contacts company and requests, in writing, that continued storage of Kleptose is no longer necessary.

SIGA agrees to pay to Company according to the terms set forth in Paragraph 4 of the above-referenced SA.

Term of this Exhibit

Services will commence upon execution of this Exhibit and will be completed by February 18, 2018.

SIGA Technologies, Inc.

BY: Dennis E. Hruby
NAME: Dennis E. Hruby, Ph.D.
TITLE: Chief Scientific Officer

DATE: 02 May 2013

DSM Pharmaceuticals, Inc.

BY: Laurence Thomas
NAME: Laurence Thomas
TITLE: V.P. Marketing & Sales

DATE: 10 May 2013

ATTACHMENT A



DSM Pharmaceuticals, Inc.
5900 Martin Luther King Jr. Highway
Greenville, North Carolina 27834

April 11, 2013

Stephen Priebe, Ph.D.
4575 SW Research Way
Corvallis OR 97333

Re: Scope Change – Tecovirimat (ST-246 ®) Injection - Storage Fees Revised

Dear Stephen:

Please find below the pricing for Tecovirimat (ST-246 ®) Injection monthly storage fees. The scope change includes storage at controlled room temperatures (CRT) for 2 pallets to store kleptose and ST-246 API.

Support Services		
	Price per Month	Price per Year
Monthly Storage Fee for 2 Pallets at Controlled Room Temperature	\$ 400	\$ 4,800
Total	\$ 400	\$ 4,800

The services under this Scope Change shall be conducted under and subject to the terms and conditions of the Services Agreement between SIGA and DSM dated January 12, 2012.

Please forward the SIGA scope change/exhibit to the Services Agreement and purchase order.

Please feel free to contact me at 858.945.5332 should you have any questions.

Kind Regards,

A handwritten signature in dark ink, appearing to read "Diane V. Lever", is written over a light blue horizontal line.

Diane V. Lever
Sr. Account Director/Business Development

cc: Jennifer Adams DSM
Shumena Horton DSM
Kaye Byrd DSM
Judy Moore DSM
Kady Honeychurch SIGA

Page 1 of 5

**Exhibit Q to the
Services Agreement
Dated 12 January 2012**

Statement of Work #17

This Exhibit details the services that Company will provide to SIGA. The services under this Exhibit shall be conducted under and subject to the terms and conditions of the Services Agreement between SIGA and Company, hereinafter ("SA").

Scope of Services

The Scope of Services is applicable to Support Services as outlined in the **Procedure Optimization Proposal Analytical** dated 10 January 2014 attached hereto as Attachment A.

Deliverables

1. Draft report to include findings from prior data and proposed experimental studies
2. Experimental studies (include injection of SG2 standard solutions and associated blanks in two different LC systems (HP and Waters))
3. Final report to include the results of the experimental studies
4. Revisions to all three current analytical standards (liquid and lyo formulations)

Payment Terms

Total charges for professional service fees and direct expenses will not exceed **\$13,900**. Company shall invoice SIGA in full upon SIGA acceptance of the 4 Deliverables listed above.

SIGA agrees to pay to Company according to the terms set forth in Paragraph 4 of the above-referenced SA.

Term of this Exhibit

Services will commence upon execution of this Exhibit and will be completed by June 2014.

SIGA Technologies, Inc.

BY: Dennis E. Hruby
NAME: Dennis E. Hruby, PhD.
TITLE: Chief Scientific Officer

DATE: 24 Feb. 2014

DSM Pharmaceuticals, Inc.

BY: Jamie Thomas
NAME:
TITLE:

DATE: 5 March 2014

Page 2 of 5

ATTACHMENT A



Page 3 of 5

January 10, 2014

Steve Priebe
Associate Director, CMC Project Coordination & Analytical
SIGA Technologies, Inc.
4575 SW Research Way
Corvallis OR 97333

Dear Steve,

Siga Technologies, Inc. has requested DSM Pharmaceuticals to generate a draft proposal to conduct a review of prior data (including the method validation, earlier stability time points, HPLC instrument, solvents, reagents, etc.) and limited experimental studies to establish a suitable procedure for quantitation of SG2. The experimental studies would include preparation and injection of SG2 standard, along with demonstration of the proposed procedure on representative HPLC instruments. The analytical procedure would be updated. No changes to the method that would affect validation should be made, e.g., no change to column, mobile phase, gradient, etc. However, minor modifications such as sample diluent, re-equilibration time, solvent grade, etc., can be considered.

The outline below provides the general rationale for this proposal request:

SG2 is a key degradant monitored in the stability studies. Recently, unexpected levels of SG2 have been reported for some stability samples, e.g., lyo formulation at 12 months. The peak in question was also observed in the blank and standard injections. DSM followed the procedure (GVL-4075) which stated to subtract the diluent peak area of the SG2 peak from the area of same peak in the sample. Since the procedure did not dictate which diluent injection should be used in the calculation, the worst case approach was taken, choosing the diluent injection with the least peak area to determine the amount of SG2 from the sample injections. Upon review of the chromatograms, it can be seen that there is a small peak in all injections at the approximate retention time of SG2. This peak seems to have shifted, compared to the experience during method validation. The peak position may be dependent upon the type of HPLC system used. Since detection is at 224 nm, there is potential for small amount of contaminant collecting on column to be observed at level similar to the degradation product. It is likely that the reported apparent SG2 peaks are artifacts, based on several other pieces of information. The apparent level is lower in the 25C sample than in the 5C sample. No SG1 Diacid (corresponding degradation product) was detected in the same samples by the sensitive LC-MS method. The reference standard is not known to contain any SG2. Other lyo stability studies at SIGA have not shown much, if any, degradation at 12 months at 5C or 25C.

Since SG2 is a peak monitored on stability, it is important to design the analytical procedure to handle it correctly to produce optimum accuracy and reproducibility. Options include:

- a. Modification of procedure to specify use of average diluent peak area for subtraction from any peak observed in the sample.

- b. Modification of system suitability requirements to specify that the area of any apparent peak in the diluent injection with RRT similar to that of SG2 should be negligible (e.g., <0.05%).
- c. Include injection of low level SG2 standard in the procedure as a reference for identification.
- d. Modify procedure in minor way, such as diluent, re-equilibration time, grade of solvent, temperature control, etc., to achieve baseline with no or negligible peak at RRT of SG2.

All pending updates to the Analytical Standard will be processed at the same time. The pending updates include:

- 1. Appearance reporting
 - a) Document actual appearance observed in the comments field, e.g., colorless/pale yellow/off-white
 - b) In case of failure or unexpected result, document the appearance result and reference the investigation, e.g., visible particles / glass fragments, PTR 226113
- 2. Hydrazine reporting
 - a) Report any amount found to 1 or 2 decimal places in the comments field, or <LOQ (0.25 ppm). [Continue reporting to 0 decimal places in result field]. Do not report numerical results less than the LOQ.
- 3. Particulate Matter
 - a) Add customer alert limit.
 - b) Specify actions to be taken if high values are obtained, such as microscopy.
 - c) Modify test method : add procedures for diluted samples - larger volume, degassing etc.
- 4. pH
 - a) Revise GM-565 and GM-566 limits (4.0 - 7.0) to match AS 4093 (3.5 - 7.0). Note: CTM batch at 3 months had values of 3.8 and 3.9.
- 5. HPLC assay & related substances method
 - a) Add note - do not use amber vials

The costs are summarized in the table below:

Support Services	Price
Draft a report to include findings from prior data and proposed experimental studies.	\$2,700
Executing experimental studies (include injection of SG2 standard solutions and associated blanks in two different LC systems (HP and Waters) The results of the experimental studies shall include recommendation(s) for HPLC procedure revisions to address SG2 issue. SIGA shall review and approve the proposed revisions.	\$3,300
Issuing a final report to include the results of the experimental studies.	\$1,400
Revised all three current analytical standards (liquid and lyo formulations).	\$6,500
Total	\$ 13,900

Page 5 of 5

No experimental work should be initiated until funding approval is provided by SIGA.

All services and/or work to be performed pursuant to this proposal shall be performed or supplied subject to the terms and conditions set forth in the Supply Agreement dated January 12, 2012 between Siga Technologies, Inc. and DPI (or DSM Pharmaceuticals Inc. where applicable), as amended by Amendment No. 1 dated January 17, 2013 and such terms and conditions shall specifically be incorporated in and be applicable to this proposal unless otherwise agreed by the Parties in writing.

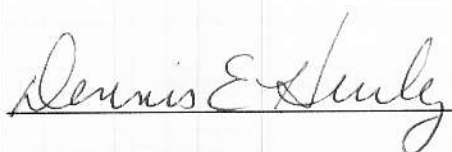
DSM Pharmaceuticals, Inc. wishes to thank Siga Technologies, Inc. for the consideration of our experience, expertise and Commitment to Excellence.

Sincerely,



Masha Kononov
Account Manager
Phone: 919-961-8189

Customer Approval:

 Date: 24 Feb 2014

DSM Pharmaceuticals, Inc.
P. O. Box 1887
Greenville, NC 27835-1887
Phone 252-758-3436

3 of 3

Page 5 of 5



4575 SW Research Way, Suite 230
Corvallis, Oregon 97333

January 3, 2013

Diane Lever
Sr. Account Director/Business Development
5900 Martin Luther King Jr. Hwy
Greenville, NC 27834

Re: Letter Amendment No. 1 – Extension of Master Service Agreement

Dear Ms. Lever,

SIGA Technologies, Inc. (hereinafter referred to as "SIGA") and DSM Pharmaceuticals, Inc. (hereinafter referred to as "COMPANY") are parties to a Master Service Agreement with an Effective Date of January 12, 2012 (hereinafter referred to as the "Agreement"). As SIGA and COMPANY have an ongoing interest in continuing Services under the Agreement, we propose that the Agreement be amended and extended as follows:

By amending the first sentence in Section 3 (Term and Termination) of the Agreement, to read:

"The term of this Agreement shall commence on the Effective Date and continue until the later of (i) the two-year anniversary of the Effective Date or (ii) the date that work under all Statements of Work issued hereunder have been completed, unless the Parties mutually agree to extend this Agreement."

To effectuate this extension, we ask that you agree that this Letter Amendment No. 1 be considered a written document, in full accordance with the manner of amending the Agreement. This Letter Amendment No. 1 shall be effective as of the date of last signature below. Except as amended herein, all other terms and conditions of the Agreement shall remain the same and in full force and effect.

SIGA TECHNOLOGIES, INC.

By: Dennis Hruby
Dennis Hruby, Ph.D.
Chief Scientific Officer

DSM PHARMACEUTICALS, INC.

By: Laurence Thomas
Name: Laurence Thomas
Title: VP Marketing and Sales

Date: 07 Jan 2013

Date: 17 Jan 2013

Letter Amendment No. 1 – Extension to Service Agreement
(Effective Date of January 12, 2012)

SIGA 4575 SW Research Way, Suite 230, Corvallis, OR 97333
Tel 541.753.2000 Fax 541.753.9999 siga.com



4575 SW Research Way, Suite 230
Corvallis, Oregon 97333

December 4, 2013

Masha Kononov
Account Manager
5900 Martin Luther King Jr. Hwy
Greenville, NC 27834

Re: Letter Amendment No. 2 – Extension of Master Service Agreement

Dear Ms. Kononov,

SIGA Technologies, Inc. (hereinafter referred to as "SIGA") and DSM Pharmaceuticals, Inc. (hereinafter referred to as "COMPANY") are parties to a Master Service Agreement with an Effective Date of January 12, 2012 (hereinafter referred to as the "Agreement"). As SIGA and COMPANY have an ongoing interest in continuing Services under the Agreement, we propose that the Agreement be amended and extended as follows:

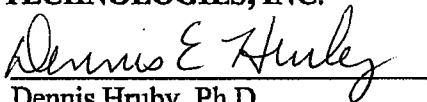
By amending the first sentence in Section 3 (Term and Termination) of the Agreement, to read:

"The term of this Agreement shall commence on the Effective Date and continue until the later of (i) the three-year anniversary of the Effective Date or (ii) the date that work under all Statements of Work issued hereunder have been completed, unless the Parties mutually agree to extend this Agreement."

To effectuate this extension, we ask that you agree that this Letter Amendment No. 2 be considered a written document, in full accordance with the manner of amending the Agreement. This Letter Amendment No. 2 shall be effective as of the date of last signature below. Except as amended herein, all other terms and conditions of the Agreement shall remain the same and in full force and effect.

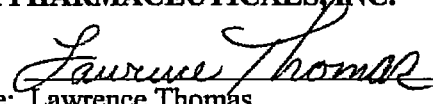
SIGA TECHNOLOGIES, INC.

By:


Dennis Hruby, Ph.D.
Chief Scientific Officer

DSM PHARMACEUTICALS, INC.

By:


Name: Lawrence Thomas
Title: VP Marketing & Sales

Date:

21 Jan 2014

Date:

01-10-2014

Letter Amendment No. 2 – Extension to Service Agreement
(Effective Date of January 12, 2012)

SIGA 4575 SW Research Way, Suite 230, Corvallis, OR 97333
Tel 541.753.2000 Fax 541.753.9999 siga.com



DSM Pharmaceuticals, Inc.

5900 Martin Luther King Jr. Hwy.
Greenville, NC 27834

www.dsm.com

March 6, 2014

SIGA Technologies, Inc.
4575 SW Research Way
Suite 230
Corvallis, OR 97333
Attn: Shantha Kumar Ph.D.

**Re: Master Services Agreement, dated 1/12/2012
(the "Agreement")
Notice of Assignment**

Dear Sir/Madam,

As you may be aware, Royal DSM ("DSM"), the parent company to DSM Pharmaceuticals, Inc. ("DPI"), has entered into an agreement with JLL to combine DSM's business group, DSM Pharmaceutical Products, Inc. ("DPP"), with Patheon, Inc. (the "Transaction"). As part of the Transaction, all of the assets of DPI will be transferred into a new entity, DPI NewCo LLC (hereinafter, "DPIN"). Upon the closing of the Transaction, which is intended to be completed on or around March 11, 2014, DSM will combine DPIN, DPP, and other pharmaceutical business units of DPP with Patheon to form a new company (which will be called DPX) in which JLL will be a majority shareholder and DSM will be a minority shareholder. The DPI legal entity will be retained by DSM, but the assets of the business will be transferred to DPIN, which will become a part of DPX. As part of the Transaction, DPI and DPIN are entering into an assignment and assumption agreement whereby all of DPI's agreements will be assigned to and assumed by DPIN effective as of the closing date of the Transaction. DPX will be comprised of three distinct business units including (i) Patheon, which will consist of the combined commercial manufacturing (CMO) capabilities and pharmaceutical development services (PDS), as well as the Biologics and Biosolutions businesses, (ii) DSM Fine Chemicals, which will include the active pharmaceutical ingredients (API) business as well as the ES/IM activities that are primarily comprised of agricultural and crop protection chemicals and specialty intermediates, and (iii) Banner Life Sciences, which continue as a proprietary products business.

This letter serves as formal notice that the above-referenced Agreement as well as any accompanying quality agreement(s), stability agreement(s), non-disclosure agreement(s), and other ancillary agreement(s) will be assigned to DPIN as of the closing of the Transaction, and that, following the closing of the Transaction, DPIN agrees to assume all of the rights and obligations provided in the Agreement and any accompanying quality agreement(s), stability agreement(s), non-disclosure agreement(s), and other ancillary agreement(s).

Further, we would like to inform you that, in addition to the new legal entity, our banking information will change as follows:

Bank account information

For payment by check:

DPI NewCo LLC
6452 Collections Center Drive
Chicago, IL 60693-0001

ACH payments:

Bank of America
100 W 33rd Street
New York, NY 10001
Credit: DPI NewCo LLC
Account #: 8188295553

Federal Reserve Wire payments:

Bank of America
100 W 33rd Street
New York, NY 10001
Credit: DPI NewCo LLC
Account #: 8188295553



ABA/Routing #: 071000039

ABA #: 026009593

Please ensure that your accounts payable group has this information and that your ERP system is updated with the above bank account information to help ensure a smooth transition. The new bank account information is acceptable for processing as early as March 1, 2014. Accordingly, we ask that you make the changes within your systems as soon as possible.

If you have any questions, please contact your Account Manager or Larry Thomas directly at larry.thomas@dsm.com. We value your business and look forward to continuing to supply your needs as we transition to a new and exciting company with a wide variety of products and services that we can offer our customers.

Sincerely,

DSM Pharmaceuticals, Inc.

By:

A handwritten signature in black ink, appearing to read "Hugh Welsh", written over a horizontal line.

Name: Hugh Welsh
Title: President

DPI NewCo LLC

By:

A handwritten signature in black ink, appearing to read "Larry Thomas", written in a cursive style.

Name: Larry Thomas
Title: Global VP Sales and Marketing

DPI NewCo LLC

5900 Martin Luther King Jr. Hwy.
Greenville, NC 27834

May 15, 2014

SIGA Technologies, Inc.
4575 SW Research Way
Suite 230
Corvallis, OR 97333
Attn: Shantha Kumar Ph.D.

**Re: Master Services Agreement, dated 1/12/2012
(the "Agreement")
Notice of Assignment**

Dear Sir/Madam,

As you may be aware, on March 11, 2014, Royal DSM, the parent company to DSM Pharmaceuticals, Inc. ("DPI"), entered into an agreement with JLL, the majority shareholder of Patheon Inc., to establish DPx Holdings B.V. ("DPx"), which combined DSM's business group, DSM Pharmaceuticals Products, Inc. ("DPP"), with Patheon Inc. (the "Transaction"). DPx is comprised of three distinct business units including (i) Patheon, which consists of the combined commercial manufacturing (CMO) capabilities and pharmaceutical development services (PDS), as well as the Biologics and Biosolutions businesses, (ii) DSM Fine Chemicals, which includes the active pharmaceutical ingredients (API) business as well as the ES/IM activities that are primarily comprised of agricultural and crop protection chemicals and specialty intermediates, and (iii) Banner Life Sciences, which is a proprietary products business.

As part of the Transaction, on March 11, 2014, all of the assets and agreements of DPI were transferred and assigned to a new entity, DPI NewCo LLC ("DPIN").

In connection with ongoing integration activities and in order to optimize DPx's internal corporate structure, on May 31, 2014, all of the assets and agreements held by DPIN (the Greenville site operations) will be transferred to Patheon Manufacturing Services LLC, a wholly-owned operating subsidiary of DPIN. Both DPIN and Patheon Manufacturing Services LLC are wholly-owned subsidiaries of DPx. The site will continue to operate business as usual; the only change will be that it will operate under the name "Patheon Manufacturing Services LLC."

This letter serves as formal notice that the above-referenced Agreement as well as any accompanying quality agreement(s), stability agreement(s), non-disclosure agreement(s), and other ancillary agreement(s) will be assigned to Patheon Manufacturing Services LLC as of the May 31, 2014 and that, following May 31, 2014, Patheon Manufacturing Services LLC agrees to assume all of the rights and obligations provided in the Agreement and any accompanying quality agreement(s), stability agreement(s), non-disclosure agreement(s), and other ancillary agreement(s).

As we work through this integration process we will be providing notice to applicable regulators within the required time frame of the corporate name change to "Patheon Manufacturing Services LLC" to ensure that there is no impact on our permits and regulatory filings.

We recognize that you may have referenced DSM Pharmaceuticals Inc. and/or DPI Newco LLC as the manufacturer of your products in applicable filings with the FDA, Health Canada or other regulatory authorities. We would advise you to review your regulatory filings and obtain advice on whether there are any implications to your filings as a result of the changes noted above. Please note that that effective May 31, 2014 your regulatory filings should be updated to note "Patheon Manufacturing Services LLC" as the manufacturer of your product. Our Quality Department will be working closely with you in the coming weeks to determine changes to artwork and labeling which may be required as a result of this change.

Further, we would like to inform you that, although our banking account information has not changed, the reference name for such account has changed. Complete banking information is noted below.

Bank account information

For payment by check:

Patheon Manufacturing Services LLC
6452 Collections Center Drive
Chicago, IL 60693-0001

ACH payments:

Bank of America
100 W 33rd Street
New York, NY 10001
Credit: Patheon Manufacturing
Services LLC
Account #: 8188295553
ABA/Routing #: 071000039

Federal Reserve Wire payments:

Bank of America
100 W 33rd Street
New York, NY 10001
Credit: Patheon Manufacturing
Services LLC
Account #: 8188295553
ABA #: 026009593

Please ensure that your accounts payable group has this information and that your ERP system is updated with the above bank account information to help ensure a smooth transition.

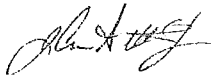
If you have any questions, please contact your Account Manager. We value your business and look forward to continuing to supply your needs as we integrate to a new and exciting company with a wide variety of products and services that we can offer our customers.

Sincerely,

DPI NewCo LLC.

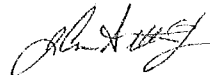
Patheon Manufacturing Services LLC

By:



Name: J. Carson Sublett, Jr.
Title: General Manager

By:



Name: J. Carson Sublett, Jr.
Title: General Manager

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QUALITY AGREEMENT

By and Between

Siga Technologies, Inc.

4575 SW Research Way, Suite. 230
Corvallis, Oregon 97333
(Hereinafter called "SIGA")


DSM Pharmaceuticals, Inc.

5900 Martin Luther King Jr. Highway
Greenville, North Carolina 27834
(Hereinafter called "DSM")

And

 31 Aug 2012
Date:

Laura J. Linscott
Director,
Quality Assurance

 9-4-12
Date:

Warren Horton
Vice President,
Quality Operations & Regulatory Affairs

This quality agreement is effective when signatures of all parties are complete.

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APPENDIX I: Product Listing
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APPENDIX III: Batch Document Review
APPENDIX IV: Revision History

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This Quality Agreement defines the roles and responsibilities of SIGA and DSM in order to maintain cGMP compliance when providing services and/or Products for SIGA. This Quality Agreement shall be incorporated within and constitute a part of the Master Services Agreement by and between SIGA and DSM and shall continue in force and effect until the Services are completed under the Master Services Agreement (including applicable Statement of Works). In the event of inconsistencies between this Quality Agreement and the Master Services Agreement, the Master Services Agreement shall control except with respect to quality assurance requirements, which shall be controlled by this Quality Agreement.

This Quality Agreement takes the form of a detailed checklist of the activities associated with pharmaceutical production and related support activities. Responsibility for each activity is assigned to either SIGA and/or DSM in the appropriate box in the Responsibility Delegation Checklist. For each responsibility listed, the respective party is required to put into effect all applicable procedures and to take all necessary actions to effectuate that responsibility in accordance with cGMP's and applicable laws.

No changes to the terms of this Agreement may be made unless by written amendment, mutually agreeable to both parties, attached hereto and made a part hereof. The parties will review the Quality Agreement upon the issuance of each Statement of Work under the Master Services Agreement to incorporate changes in services and/or Product(s) and issue a revised document or appendix, as appropriate. The Product(s) referred to herein as Product and the Product development stage (i.e. development, clinical trial material) are defined in Appendix I. To facilitate routine communications between the parties, company contact individuals are provided in Appendix II. SIGA and DSM contact individuals may be updated as required by notification to either party.

This Quality Agreement shall expire upon the expiration or termination of the Master Services Agreement, except those obligations, which, by their nature, shall survive the expiration or termination of this Quality Agreement, such as ongoing regulatory requirements set forth in this Quality Agreement, and including, for example, maintaining records and supporting product complaint investigations.

RESPONSIBILITY DELEGATION CHECKLIST

Responsibilities		SIGA	DSM
1 GMP STANDARDS			
1.1	Services contracted will comply with applicable domestic and international current good manufacturing practices (cGMP) (such as USP Pharmacopoeia, European Pharmacopoeia, and other relevant international, federal, state, and local laws and regulations) appropriate to the product development stage and distribution.		√
1.2	Will provide prior notification when changing the country of market and to ensure existing product operations comply with the specific market and applicable regulations.	√	
1.3	Agrees to comply with policies and procedures adopted by DSM to establish and maintain cGMP, including investigative methodology that governs how DSM interprets	√	

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Responsibilities		SIGA	DSM
	and releases data in support of final batch disposition.		
2 QUALITY PRESENCE			
2.1.	Shall work collaboratively to conduct periodic meetings to discuss Product quality-related data, future planning, regulatory updates, and such other matters as may be requested by a Party and agreed by the other Party.	√	√
2.2	Will permit SIGA to perform a minimum of one (1) standard cGMP biennial compliance audit for the services contracted, upon reasonable notification from SIGA, with actual audit dates subject to mutual agreement. Such audits shall not exceed two (2) business days and shall have no more than four (4) auditors. SIGA representatives will be escorted by DSM personnel at all times and will only have access to the facility and records relating to the services and Products under contract with SIGA. When the work being performed is funded under a contract with the United States Government (USG), DSM will allow SIGA representatives to be accompanied by employees of or contractors to the USG as observers of the audit.		√
2.3	Notwithstanding the foregoing, will permit SIGA to conduct additional audits on a date mutually agreed upon by both parties to the extent necessary to address significant product quality or compliance problems. Such audits shall be scheduled promptly after notice from SIGA following a quality or safety occurrence.		√
2.4	Will report audit findings verbally at the close of the audit and will provide a written report within thirty (30) calendar days of the audit.	√	
2.5	Response will include root cause evaluation, corrective actions, preventative actions, and remedial actions, where appropriate, and shall include a timeline for completion of each action. The response will be sent to SIGA within thirty (30) calendar days from report receipt or in a mutually agreed upon time period.		√
3 REGULATORY AGENCY INSPECTIONS			
3.1	Will notify SIGA within one (1) business days of any regulatory agency action that specifically affects the contracted services and/or Products to be supplied pursuant to the Master Services Agreement.		√
3.2	Notify SIGA of any regulatory agency inspection specifically impacting the products covered by this Agreement within one (1) business days of initiation of the audit by the regulatory agency.		√
3.3	Reserves the right to be available on site during an agency inspection when the inspection pertains to Product.	√	
3.4	Will respond to the regulatory agency after consultation with SIGA on any SIGA product-specific citations. Upon request, DSM will forward appropriately redacted regulatory agency documentation (e.g., EIR) and responses that pertain to SIGA products to SIGA within ten (10) business days of request or completion of submission.		√
3.5	Notify DSM of any regulatory agency inspection specifically impacting the products covered at SIGA or affiliate by this Agreement within two (2) business days of the initiation of the audit by the regulatory agency.	√	
3.6	Reserves the right to present site data and/or procedures upon specific requests regarding DSM responsibilities.		√

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Responsibilities		SIGA	DSM
4 PREMISES			
4.1	Will perform pharmaceutical production and related support activities at the facility.		√
4.2	Will maintain premises and equipment used to manufacture the Products according to current regulatory requirements.		√
4.3	Manufacture the Products in a suitably controlled environment; and such facilities will be regularly monitored for parameters critical to the process in order to demonstrate and maintain compliance with (i) applicable GMP guidelines and (ii) mutually agreed specifications.		√
4.4	Will maintain controlled access to the premises. All visitors shall comply with applicable access policies, dress code, cell phone usage, camera, security, and safety requirements.		√
4.5	<p>Restrict the following product types (classification) from being introduced as noted into the existing common site manufacturing operations.</p> <ul style="list-style-type: none"> • Insecticides/Pesticides • Live Organisms (Live or attenuated virus) • Beta Lactams, Penicillin, and Penicillin derivatives • Non-Treated Blood Product • Hormones • Cytotoxic* <p>*Segregated site manufacturing option available for product classification</p>		√
4.6	Will notify DSM of any commitments and/or restrictions associated with the manufacturing of the Products in a multiple-product manufacturing facility. In the event that SIGA identifies a potential regulatory requirement related to a new product introduction that would affect Product activity, the parties will identify actions to resolve the requirement.	√	
4.7	Will notify agencies, as appropriate, of intent to produce, package, label, warehouse, quality control test, release or ship any new product at the facility classified within the prohibited or highly active compounds in accordance with the regulations and other requirements of the agencies.		√
5 TRAINING / QUALIFICATION			
5.1	Shall maintain a program to assure that all personnel engaged in the operations related to the PRODUCTS have the education, training, and experience to properly perform their assigned functions in compliance with cGMP.		√
5.2	Training shall be in the particular operations that the employee performs and in current applicable manufacturing regulations, as they relate to the employee's functions.		√
5.3	Training records for all personnel shall be maintained and made available upon request by SIGA, or pursuant to any regulatory review.		√
6 DOCUMENTATION AND CHANGE MANAGEMENT			

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Responsibilities		SIGA	DSM
6.1	All changes to the Product related documents (i.e. master batch record, analytical method) shall proceed through a technical and cGMP impact assessment according to DSM's change control program.	√	√
6.2	The documents which (a) contain changes that may, in SIGA's reasonable judgment, affect SIGA's regulatory submissions or the support system and which (b) have a direct impact on the quality systems affecting SIGA's Product will also be reviewed and assessed by SIGA's designated personnel for regulatory advice and implementation requirements and such approval shall not be unreasonably withheld or delayed. If there is any doubt regarding which documents affect SIGA's Product, DSM shall contact SIGA for a determination prior to implementation.		√
6.3	Shall not make any changes to DSM-owned or DSM-controlled cGMP documentation without the consent of DSM in order to ensure that all cGMP documentation, which is maintained at DSM and subject to regulatory review, is consistent with information filed with regulatory authorities.	√	
7 RAW MATERIAL/ PACKAGING COMPONENTS			
7.1	Shall provide specifications to DSM for raw materials/primary packaging components to be supplied by DSM.	√	
7.2	Shall be responsible for using raw materials/primary packaging components from approved vendors, qualified according to DSM procedures, agreed upon by both parties.		√
7.3	Shall be responsible for qualifying API vendor and will provide DSM with a Certificate of Compliance statement for such vendor upon request.	√	
7.4	Shall be responsible for ensuring that all raw materials / primary packaging components and related testing information supplied by SIGA or by its designated vendors for use in manufacture of the Products are in full compliance with the specifications registered.	√	
7.5	Shall be responsible for ensuring that all raw materials / packaging components from DSM designated vendors for use in manufacture of the Products are in full compliance with the specifications provided by SIGA.		√
7.6	Shall provide a Certificate of Analysis for materials supplied directly by SIGA.	√	
7.7	Will provide details of any storage and shipping conditions for the API.	√	
7.8	Will store API and raw materials in accordance with specifications.		√
7.9	SIGA shall review and approve all Product specific raw materials and primary packaging component specifications.	√	
7.10	Prior to use, all raw material / packaging components must be found to meet specifications.		√
7.11	Will control API and raw materials that have been rejected by SAP system segregation.		√
7.12	Will utilize where practicable, components in a "First Expired, First Out" basis (i.e. the oldest materials will be consumed first in production operations).		√
8 LABORATORY ANALYSIS			

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Responsibilities		SIGA	DSM
8.1	SIGA shall be responsible for providing approved copies of the current and complete regulatory filed analytical methods.	√	
8.2	DSM shall be responsible for method validation relating to the Products for application in the production process, including in-process product testing and product batch release per the regulatory guidance documents for the phase of development (Phase I/II).		√
8.3	Supply any required reference standards that are not readily available through a commonly recognized source. Such reference standards must be accompanied by a Certificate of Analysis listing the expiration date and any correction factors that need to be applied.	√	
8.4	May perform confirmatory testing during the initial term of this Agreement to validate the DSM data. Periodically thereafter, may test material to confirm the DSM data. Dispute resolutions in conflicting test data will be handled according to Section 22.	√	
8.5	Will provide SIGA with a Certificate of Analysis for testing services performed at DSM. In the event that SIGA is either performing or subcontracting release testing to an outside laboratory, DSM will release the product as defined in Section 16.		√
8.6	Will perform sterility and bacterial endotoxin testing at a minimum for parenteral products produced within DSM.		√
9 FINISH PRODUCT STABILITY			
9.1	Responsible for maintaining a routine stability program for the Products. The stability activities (contract storage, contract testing) will be defined in a separate stability agreement that will identify the storage requirements, testing responsibilities, testing specifications and methods, testing intervals, and bracketing, if applicable.		√
9.2	Any Out of Specifications ("OOS") occurrences that are confirmed according to the stability program will be communicated to SIGA within one (1) business day and DSM shall provide assistance as required for regulatory reporting purposes. Any Out of Specification occurrence identified will follow the DSM investigation process and procedures as defined in Section 14.		√
10 RETENTION OF SAMPLES			
10.1	Will retain API samples following procedures that are in accordance with regulatory guidelines and will not unreasonably withhold sample analysis support if DSM requests related to an investigation or other extenuating circumstance.	√	
10.2	Will retain DSM procured excipient samples following procedures that are in accordance with regulatory guidelines.		√
10.3	Will retain finished Product samples following procedures that are in accordance with regulatory guidelines.		√
10.4	Will retain a reference sample of the Products representing DSM operations for a defined retention period.	√	
10.5	Will notify SIGA prior to destruction of any product at the completion of the retention period.		√
10.6	May designate materials to be shipped to a designated location beyond the DSM	√	

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Responsibilities		SIGA	DSM
	retention period.		
11 VALIDATION			
11.1	Responsible for gathering data on critical CTM parameters to support commercial process validation requirements.	√	√
11.2	Prepare a technical document outlining the development and transfer activities (container closure integrity, component qualification, machinability, sterilization process, cleaning process, etc.) of any specified product(s) into DSM's facility.		√
11.3	Will ensure via verification that cleaning processes carried out on PRODUCT contact surfaces between batches of different products and raw materials are adequate to prevent contamination within the requirements outlined in quality policies. Data should be available to support the campaign of batches of the same product and the type of cleaning that will be performed in between manufacturing of the same product.		√
11.4	Will provide required information (i.e. LD50, toxicity, solubility, batch size, fill volume, product min dose/70Kg patient) to establish cleaning limits.	√	
11.5	Responsible for all laboratory, equipment, computer, facility, and utility qualification activities associated with the Products. Will include back-up power for cold storage operations in conjunction with contingency processes, as applicable for Products.		√
12 CALIBRATION/PREVENTATIVE MAINTENANCE			
12.1	Will maintain a calibration and preventative maintenance program to support the manufacturing, testing, packaging and storage of Products.		√
12.2	Shall maintain and follow a procedure that documents the actions to be taken in the event of a calibration failure.		√
12.3	Investigate deviations from approved standards of calibrations to determine if these deviations could have an impact on the quality of the Product and notify SIGA as required per Section 14.		√
13 SUBCONTRACTING			
13.1	Any subcontracted laboratory or manufacturing facility for the Product must be approved by SIGA prior to being used by DSM.		√
13.2	DSM will audit such subcontractors to determine compliance with cGMP according to DSM's criteria, which may differ from the criteria in the contractor quality agreement with SIGA. Any discrepancies will be discussed with SIGA.		√
14 INVESTIGATIONS			
14.1	Responsible for investigating any testing performed by DSM that is confirmed as a failure to meet Product specifications (i.e. out of specification) and will follow internal procedures that are in accordance with regulatory guidelines.		√
14.2	Will support investigation request for any testing performed by SIGA that is confirmed as a failure to meet Product specifications (i.e. out of specification) and will follow internal procedures that are in accordance with regulatory guidelines.		√
14.3	Responsible for investigating any deviation from the process during manufacture and		√

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Responsibilities		SIGA	DSM
	will follow internal procedures that are in accordance with regulatory guidelines.		
14.4	Will notify SIGA within one (1) business days of any Product Testing Record (PTR) or Deviation Management Record (DMR) initiated related to Product.		√
14.5	DSM will provide the PTR or DMR to SIGA for review and approval.		√
14.6	SIGA will provide comments and/or approval within five (5) business days. If no response is received, DSM will proceed to complete the investigation without SIGA approval. A copy of the closed investigation will be provided upon completion.	√	√
14.7	As the Product license holder and technical Product/process expert provide technical and/or Product quality assessments in support of investigations, if required.	√	
14.8	In the event that a Product or customer provided material will be rejected, DSM will notify SIGA to discuss the product disposition.		√
14.9	Will notify SIGA within 24 hours if any problems are discovered that may affect Product batches shipped in order to assure that regulatory reporting guidelines may be met.		√
15 BATCH DOCUMENTATION REVIEW			
15.1	Will provide a standard Certificate of Analysis indicating the test results performed by DSM as well as a signed Certificate of Compliance confirming that the Products have been manufactured, tested, and stored according to the requirements of the Master Production Record and cGMP criteria.		√
15.2	Will provide a list of any Product testing record, manufacturing deviation, and material deviation as part of the release documentation package.		√
15.3	Will provide complete batch documentation (Manufacturing Work Order, Filling Work Order, and Packaging Work Order) copies to SIGA. Copies of analytical raw data from batch testing through validation of the commercial manufacturing process will be provided; including notebook pages and chromatograms sufficient to confirm the testing was performed correctly and verify calculated results. Summary results can be provided for endotoxin and sterility testing, with additional details upon request.		√
15.4	Changes to the batch review process may occur at any time with written agreement as defined in Appendix III.	√	√
15.5	Batch documentation listed above will be provided to SIGA within six (6) weeks after filling date.		√
15.6	SIGA will review batch documentation and provide final disposition of the Product to DSM within two (2) business days of resolution of any issues from the review.	√	
15.7	Final certificate of compliance will be provided within two (2) business days following SIGA disposition.		√
16 PRODUCT DISPOSITION			
16.1	Responsible for release to clinical trial studies and further distribution of the Products once dispositioned by DSM for release.	√	
16.2	Will release the Product to SIGA for shipment if all pre-defined release criteria are met.		√

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Responsibilities		SIGA	DSM
16.3	Changes to the shipment release process for CTM batches may occur at any time with written agreement as defined in Appendix III.	√	√
16.4	SIGA may, at its own discretion, reject a batch which DSM has dispositioned as satisfactory. However, the decision to reject shall not be based on a discrepancy between SIGA and DSM's methodologies. Any problem discovered by SIGA likely to cause rejection of the approved Products will be communicated to DSM within thirty (30) calendar days from receipt of the full release documentation package.	√	
16.5	Any disputes between the parties with respect to rejection of Product shall be resolved in accordance with Section 22 hereinafter.	√	√
17 STORAGE AND SHIPMENT			
17.1	Will store the Products under conditions specified by Product label requirements as supplied by SIGA. Product storage areas will be continuously monitored.		√
17.2	Will ensure that during storage before shipping of the Products, appropriate controls are in place to ensure that there is no interference, theft, product contamination, or mixture with any other products or materials.		√
17.3	Will provide details of any Product shipping requirements (i.e. labeling, container sealing and integrity, shipment monitoring, storage, and shipping conditions) based upon SIGA's shipping qualification requirements.	√	
17.4	Label and package Product for transit pursuant to instructions provided in writing by SIGA that comply with cGMP and other applicable regulations (e.g., OSHA, DOT).		√
17.5	SIGA will provide Shipment Authorization.	√	
17.6	Ship to the designated locations upon request from SIGA. DSM will not ship any Product that is under quarantine unless according to controlled procedures which fully comply with regulatory requirements and which are mutually agreeable between DSM and SIGA.		√
17.7	In the event that SIGA requests DSM to ship Product in quarantine, then SIGA shall supply DSM with a written certification stating, "Product will not be released to clinical trials or commerce until fully released."	√	
18 DOCUMENT RETENTION			
18.1	Shall maintain a program to assure electronic and hardcopy documents that support pharmaceutical manufacturing processes adhere to defined regulatory retention requirements, security, and controlled destruction.		√
18.2	Will retain batch records for Development and Clinical Trial Materials for fifteen (15) years from the date of manufacture of each batch.		√
18.3	Will notify SIGA prior to destruction of any executed records at the completion of the DSM retention period.		√
18.4	Will acknowledge destruction within thirty (30) calendar days by DSM procedures or coordinate the documents to be transferred to a designated location beyond the DSM retention period.	√	

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Responsibilities		SIGA	DSM
19 REGULATORY SUBMISSIONS			
19.1	Responsible for ensuring all appropriate regulatory filings and import/export documentation are filed with regulatory agencies prior to shipment/human administration.	√	
19.2	Will provide a regulatory data summary package to support applicable to CMC documents and additional regulatory filings as negotiated in the Master Services Agreement.		√
19.3	Will provide notification of the applicable Product registration changes to align DSM changes as defined in Section 1.	√	
19.4	Responsible for registering the facilities with the FDA and to maintain the registration data such that it is readily available.		√
20 COMPLAINTS			
20.1	Responsible for receiving all Product complaints and formally requesting investigation, when applicable. Notification is required to contain the following information for DSM to initiate a complaint investigation: Product(s) affected including name and strength, lot number (if available), description of the complaint, and source of the complaint.	√	
20.2	Any complaints received by DSM directly from a complainant (e.g. secondary packaging contractors, consumer, pharmacist) will be forwarded to SIGA within one (1) business day.		√
20.3	Upon receipt of the complaint notice, will perform the investigation within thirty (30) calendar days following internal procedures that are in accordance with regulatory guidelines for activities that are part of DSM processing.		√
20.4	Responsible for investigating activities occurring outside of DSM's controls (i.e. administration of the product, shipping related, counterfeiting).	√	
20.5	SIGA and DSM shall mutually agree to an expedited timeframe for complaint investigations in the event of potential regulatory-related actions or other agreed upon investigational situations.	√	√
21 REGULATORY ACTIONS			
21.1	Responsible for filing and initiating any Product regulatory action (i.e. adverse event, field alert, withdrawal, recall) due to any defect considered sufficiently serious, with data and assistance provided by DSM. Will provide DSM with a copy of any DSM relevant regulatory correspondence related to regulatory actions, redacted as applicable, associated with the manufacturing or packaging of the Product by DSM..	√	
21.2	SIGA shall be responsible for coordinating all necessary activities regarding the regulatory action taken. Accordingly, DSM and SIGA agree to cooperate fully regarding any regulatory action and the Parties agree to keep each other advised, and to exchange copies of such documentation as may be required, to assure regulatory compliance.	√	
21.3	SIGA acknowledges and understands that DSM has significant regulatory obligations as manufacturer of the Product if there are any indications that regulatory action would be necessary. DSM has the responsibility to notify appropriate regulatory agencies if		√

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Responsibilities		SIGA	DSM
	patient safety may be at risk as a result of a released batch being found to not meet filed specifications or whose Safety, Quality, Identity, Potency or Purity (SQIPP) are in question as a result of a deviation. In the event that DSM has reason to believe that market action should occur regarding the Product, DSM will provide written notification to SIGA prior to notifying the regulatory agency.		
22 DISPUTE RESOLUTION			
22.1	In the event that a dispute arises regarding the non-conformity of a batch of the Products or regarding other matters, the senior management of the quality departments shall in good faith promptly attempt to resolve disputed issues. DSM shall be responsible for determining when a batch of Product is suitable for release to SIGA and SIGA may only dispute a batch of Product after DSM has released the Product to SIGA.	√	√
22.2	If the parties cannot reach agreement, the matter shall be resolved in accordance with dispute resolution provisions of the Master Services Agreement.	√	√

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APPENDIX I: Product Listing

Product	DEVELOPMENT STAGE
Tecovirimat (ST-246 ®) Injection, 10 mg/mL	Phase I/II Clinical Trial Material

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APPENDIX II: Company Contact Individuals

SIGA Contacts

NAME/ TITLE	RESPONSIBILITY	CONTACT
Laura J. Linscott Director Quality Assurance	Quality Oversight	541-758-4832 llinscott@siga.com
Shanthakumar Tyavanagimatt VP, Drug Development/CMC	Technical Oversight	541-766-3744 shantha@siga.com
Steve Priebe Associate Director CMC Projects & Analytical	Technical Oversight	541-758-4810 Spiebe@siga.com

DSM Contacts

NAME/ TITLE	RESPONSIBILITY	CONTACT
Warren Horton Vice President, Quality Operations & Regulatory Affairs	General Quality	252.707.7710 warren.horton@dsm.com
Tami Benjamin QA Sr. Director, Steriles Manufacturing Oversight	General Manufacturing Oversight, Investigations	252.707.2765 tami.benjamin@dsm.com
Keisha Barrett Group Leader, Steriles QA Batch Record Review/Release	Batch Review/Release	252.707.2433 keisha.barrett@dsm.com
Lora Landreth Manager, QA Lab Oversight	Testing and Analysis	252.707.2138 lora.landreth@dsm.com
Beverly Garrett Manager, QA Document Control/Training	Change Control	252.707.2260 beverly.garrett@dsm.com
Kemberly Ullah Manager, QA Audits	Audits	252.707.2793 kemberly.ullah@dsm.com
Olga Batista Manager, Regulatory Affairs	Regulatory Affairs, Annual Product Review, Complaints	252.707.2309 olga.batista@dsm.com Complaint correspondence techcomplaints.DSM@dsm.com
Diane Lever Sr. Account Director	Account Manager	510.524.2852 diane.lever@dsm.com

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Appendix III: Batch Documentation Review

Batch Record Documentation

- Certificate of Analysis - reporting the DSM testing results
- Certificate of Compliance - confirming that the Products have been manufactured, tested, and stored according to the requirements of the Master Production Record and cGMP criteria.
- Deviation(s) – report list indicating all product specific deviations (i.e. Product testing record, manufacturing deviation, material deviation) that have been closed and copy of closed Deviations.
- Complete copy of the batch documentation (Manufacturing Work Order, Filling Work Order, Packaging Work Order, environmental monitoring results, etc.) for review prior to DSM release for shipment. Copies of analytical raw data from batch testing through validation of the commercial manufacturing process will be provided; including notebook pages and chromatograms sufficient to confirm the testing was performed correctly and verify calculated results. Summary results can be provided for endotoxin and sterility testing, with additional details upon request. Upon SIGA notification of review approval, DSM will release the batch making product available for shipment to SIGA.

Reduced Batch Record Review

- Certificate of Compliance
- Certificate of Analysis
- Deviation listing and copy of closed Deviations.

Transfer and terms of the reduced record review and DSM shipment release program will be approved by SIGA and DSM and documented in writing as an addendum to the quality agreement.

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APPENDIX IV: Revision History

Version	Revisions/Changes
1.0	Original